

# **EXHIBIT DX45**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS



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# Adhesion and Removal of Fine Particles on Surfaces

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Particles on surfaces containing microelectronic circuits interfere with the circuit operation thus reducing product yield. Adhesion of particles to such surface as well as to other surfaces in production environments needs to be understood so that effective ways for preventing deposition and cleaning contaminated surfaces may be devised. Adhesive forces result from molecular and electrostatic interaction and are influenced by the surrounding medium

and the composition. The magnitude of adhesive forces relative to the particle mass increases significantly for micrometer- and submicrometer-sized particles, and their removal is therefore difficult. Experimental techniques for adhesion measurement are marginal, and new developments are urgently needed. Considerable new research is needed to develop new cleaning media and techniques.

## INTRODUCTION

Forces between solids are predominantly of attractive nature and cause adhesion of particles to each other and to surfaces. These forces become increasingly significant for fine particles because the particle mass varies to the third power of the particle size. An analysis of the adhesive interactions was recently presented by Bowling (1985), and a very lucid discussion of the intermolecular and surface interactions is presented by Israelachvili (1985).

Particle adhesion phenomenon is important in a variety of scientific and engineering applications. Agglomeration resulting from particle adhesion to each other affects the particle-size distribution and physical properties of particulate systems. Effective particle removal by filtration and precipitation depends upon the ability of particles to remain on the collector surface.

Contamination of electronic components by submicrometer particles is becoming a growing concern as the industry strives to reduce size and to increase capacities. Particles are deposited on these surfaces by the combined action of diffusion, sedimentation, inertia, and other factors, such as electrical charges and local electrostatic fields. The

probability of adhesion or the "sticking coefficient" is subsequent to deposition and is the resultant of the adhesive forces and forces acting for their removal. The following discussion assumes that particles are already in contact with the surface.

The most significant surface from the contamination viewpoint in the microelectronics industry is the silicon wafer. The wafer undergoes several changes as it proceeds through several manufacturing steps. As a result, the surface composition may vary from pure silicon to oxide, and various chemical and polymeric coatings may also be applied.

Other environmental surfaces such as processing components, fluid filters, enclosures, and pipes may also come in contact with the particles and may act as a source of contaminants if these particles are released in processing operations. Adhesion and reentrainment of particles from these surfaces must also be included in the overall microcontamination control problem.

Particles in the microelectronics processing environment are deposited on surfaces from air and liquids and from human sources (e.g., skin flakes and hair). They range from about 0.1  $\mu\text{m}$  to several mi-

crometers in size and may be round or irregular grains, plate-like, or cylindrical in shape. Composition of these particles ranges from metal oxides to soil and from sand to complex organics and polymers.

The environment, either air or liquid, plays a role in the deposition and may influence the nature of the particle–surface contact zone. For example, at high humidities (relative humidity above 50%) capillary condensation may form a liquid phase in the contact zone and under right conditions increase adhesion by capillary forces. These forces are dependent on liquid surface tension, and water creates significant surface tension.

PARTICLE–SURFACE INTERACTIONS

The principal interactions that are encountered in particle adhesion include molecular interactions, electrostatic interaction, liquid bridges, double-layer repulsion, and chemical bonds such as polar and metallic bonds.

Molecular Interactions

The theories for molecular interactions are based on the van der Waals dispersive interactions. Atoms in the bodies are instantaneous dipoles, and the dispersive interactions between these dipoles and the induced dipoles in neighboring atoms are summed over all atoms. It is conveniently represented by a Hamaker constant,  $A$ . The force of adhesion is related to the Hamaker constant by the expressions shown in Figure 1 for several geometries.

The relations between the Hamaker constants of two dissimilar materials may be represented by:

$$A_{12} = \sqrt{A_{11} \cdot A_{22}},$$

where  $A_{11}$  and  $A_{22}$  are the Hamaker constants for substances “1” and “2.” In the presence of a medium denoted by “3,” the net interactions between substances 1 and 2

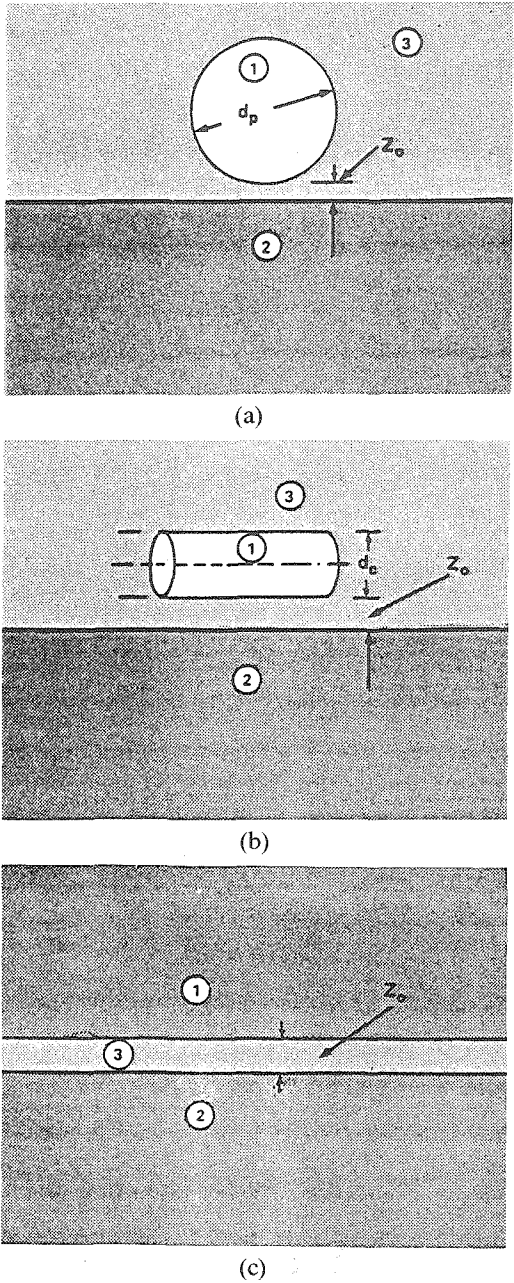


FIGURE 1. van der Waals molecular interactions: (a) sphere—planar surface,  $F_{Ad} = \frac{A_{132} d_p}{12 Z_0^2}$ ; (b) cylinder—planar surface,  $\frac{F_{Ad}}{\text{length}} = \frac{A_{132} d_c^{1/2}}{16 Z_0^{5/2}}$  (Langbein, 1972); (c) two planar surfaces,  $\frac{F_{Ad}}{\text{area}} = \frac{A_{132}}{6 \pi Z_0^3}$ .

is given by:

$$A_{132} = A_{12} + A_{33} - A_{13} - A_{23}.$$

Visser (1981) points out that it is possible to choose a medium “3” such that the net value of  $A_{132}$  is negative, resulting in repulsion! Examples of such combinations of the materials and media are rather rare and ambiguous.

There are two major theories leading to the formulation of the Hamaker constant. In the London–van der Waals theory, also known as the “microscopic theory,” the total energy of interaction between atoms is given by:

$$V_{11} = -\frac{\beta_{11}}{r^6}; \quad r - \text{distance of separation,}$$

where the constant  $\beta_{11}$  is given by:

$$\beta_{11} = \frac{3}{4} \alpha_0^2 h \nu_0,$$

where  $\alpha_0$  is the static polarizability of the atom,  $h$  is the Plank’s constant, and  $\nu_0$  is the frequency of the electrons in the ground state. Various approximations are available for computation of  $\beta_{11}$  and are summarized by Visser (1972). The principal approximation often used is based on the optical–dispersion data; i.e., refraction index versus wavelength.

The London theory is based on pairwise addition of interactions between atoms of neighboring bodies leading to the relationship:

$$A_{11} = \pi^2 q_1^2 \beta_{11},$$

where  $q$  is the number of atoms “1” per unit volume, and:

$$A_{12} = \pi^2 q_1 q_2 \beta_{12},$$

provided:

$$\beta_{12} = \sqrt{\beta_{11} \beta_{22}}.$$

The London formulation is strictly correct only for distances of separation less than 100 Å. The additivity of the interactions is also questioned.

Lifshitz developed the “macroscopic theory” based on interactions for two bodies 1

and 2, separated by a medium 3 (Krupp, 1967). The resulting expression is:

$$h\bar{\omega}_{132} = h \int_0^\infty \frac{\epsilon_1(i\xi) - \epsilon_3(i\xi)}{\epsilon_1(i\xi) + \epsilon_3(i\xi)} \cdot \frac{\epsilon_2(i\xi) - \epsilon_3(i\xi)}{\epsilon_2(i\xi) + \epsilon_3(i\xi)} d(\xi),$$

where  $\epsilon_1(i\xi)$  is the dielectric constant of material,  $i$ , along the imaginary frequency axis,  $i\xi$ . For vacuum,  $\epsilon_3$  is equal to 1. The Hamaker constant is given by:

$$A_{132} = \frac{3}{4\pi} \cdot h\bar{\omega}_{132}.$$

An example of the range of Hamaker constants of various solids is presented in Table 1. A word of caution, however, is

**TABLE 1.** Values of Lifshitz—van der Waals Constants  $h\bar{\omega}_{131}$  for Some Common Materials (Visser, 1976)

Combination	$h\bar{\omega}_{131}(\text{eV})$	
	Vacuum	Water
Homogeneous combinations		
Au–Au	14.3	9.85
Ag–Ag	11.7	7.76
Cu–Cu	8.03	4.68
Diamond–diamond	8.60	3.95
Si–Si	6.76	3.49
Ge–Ge	8.36	4.66
MgO–MgO	3.03	0.47
KCl–KCl	1.75	0.12
KBr–KBr	1.87	0.18
KI–KI	1.76	0.20
Al <sub>2</sub> O <sub>3</sub> –Al <sub>2</sub> O <sub>3</sub>	4.68	1.16
CdS–CdS	4.38	1.37
H <sub>2</sub> O–H <sub>2</sub> O	1.43	—
Polystyrene–polystyrene	1.91	0.11
Heterogeneous combinations		
Combination	$h\bar{\omega}_{132}(\text{eV})$	
	Water	Polystyrene
Au–Ag	—	8.27
Au–Cu	6.41	5.93
Au–Diamond	6.11	5.45
Au–Si	5.32	4.70
Au–Ge	6.50	5.93
Au–MgO	1.99	1.25
Au–KBr	0.73	0.00
Au–Al <sub>2</sub> O <sub>3</sub>	—	2.60
Au–CdS	—	2.65
Au–polystyrene	0.72	—

needed, because computations are subject to several different assumptions. Experimental determination is not conclusive, because the distance of separation,  $Z_0$ , is not measurable and assumptions range from 4 to 10 Å units. It should be noted that the van der Waals attraction depends on the first power of the particle diameter. Mechanical removal forces, on the other hand, are represented by “mass  $\times$  acceleration,” and thus they depend on the third power of particle diameter. For this reason, very high accelerations are required to remove small particles, as shown in Table 2. The effect of medium is shown in Table 3.

TABLE 2. Effect of Particle Size on Force of Adhesion<sup>a</sup>

Particle size ( $\mu\text{m}$ )	$F_{\text{Ad}}$ (dyn)	Particle mass (g)	Acceleration for removal (g)
10	$9 \times 10^{-2}$	$2 \times 10^{-2}$	$4.5 \times 10^4$
1	$9 \times 10^{-3}$	$2 \times 10^{-12}$	$4.5 \times 10^6$
0.1	$9 \times 10^{-4}$	$2 \times 10^{-15}$	$4.5 \times 10^8$

<sup>a</sup>Materials:  $\text{Al}_2\text{O}_3$  on  $\text{Al}_2\text{O}_3$  in air ( $h\bar{\omega} - 4.68 \text{ eV}$ ).

TABLE 3. Effect of Medium on Adhesion<sup>a</sup>

Material	Substrate	Medium	$F_{\text{Ad}}$ (dyn)
$\text{Al}_2\text{O}_3$	$\text{Al}_2\text{O}_3$	Air	$9 \times 10^{-3}$
$\text{Al}_2\text{O}_3$	$\text{Al}_2\text{O}_3$	Water	$2 \times 10^{-3}$
$\text{Al}_2\text{O}_3$	Polystyrene	Air	$5 \times 10^{-3}$
Polystyrene	Polystyrene	Air	$3 \times 10^{-3}$
Polystyrene	Polystyrene	Water	$2 \times 10^{-4}$

<sup>a</sup>Particle size:  $-1 \mu\text{m}$ .

TABLE 4. Effect of Hardness on van der Waals Adhesive Force Between a 5- $\mu\text{m}$ -Diameter Sphere and a Flat Surface at a Separation of 0.4 nm<sup>a</sup>

Hardness $H$ (dyn/cm <sup>2</sup> )	Hamaker constant $A \times 10^{12}$ (ergs)			$F_{\text{Ad}}$ (mdyn)
	0.29	0.96	4.31	
$10^6$ (Plastics)		3600	$4 \times 10^4$	—
$10^8$ (Metals)		42	400	$8 \times 10^3$
$10^{10}$ (Abrasives)		6	24	170

<sup>a</sup>From Krupp (1967).

Effects of microsurface roughness and deformation at the point of contact also make the calculation of “A” from experimental measurement ambiguous. In Table 4 the effect of hardness (or deformation) on the adhesive force was presented by Krupp (1967), and orders of magnitude variations can be attributed to deformation resulting in increased area of contact. Presence of films and trace impurities also affect the interactions.

The effect of roughness on van der Waals force is highly dependent on the nature of the roughness. The molecular interactions are usually active over distances several nanometers deep in the particle and the substrate from the interface. If surface asperities are much smaller than particles, as shown in Figure 2a, less mass is present in the immediate vicinity of the contact plane resulting in reduced adhesion force. Czarnecki and Dabros (1980) proposed a correction factor dependent on the mass distribution in the particle or substrate surface layers.

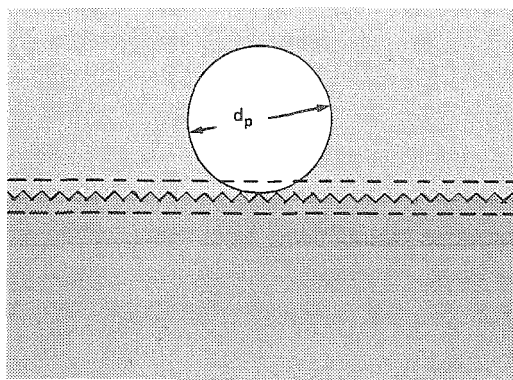
On the other hand, the situation shown in Figure 2b, the effective contact area is increased and may result in increased adhesion.

Electrostatic Interaction

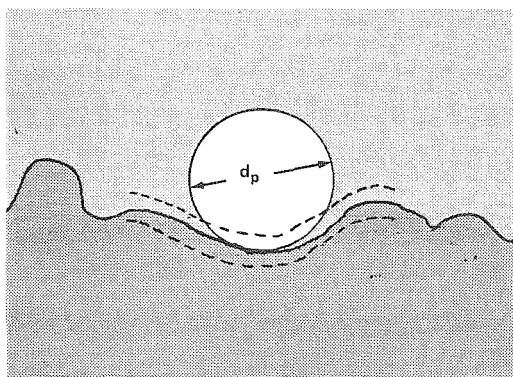
Two types of electrostatic interactions may cause increased particle adhesion. The first type arises from the difference in the work functions of two different materials resulting in a contact potential  $\phi_c$ . The contact potential has a maximum value of 0.5 V. Charges are produced in the surface layers of the particle and the surface. The force due to the electrostatic double layer is given by Krupp (1967) as:

$$F_{\text{el}} = \pi \epsilon_0 \frac{d_p}{2} \cdot \frac{\phi_c^2}{Z_0},$$

at a maximum contact potential 0.5 V and a distance of separation  $Z_0 = 4 \text{ Å}$ , the value of the force is about 1 mdyn for a 1- $\mu\text{m}$  particle. This value may become comparable to



(a)



(b)

**FIGURE 2.** Effect of surface roughness: (a) asperities smaller than particle size; (b) asperities larger than particle size.

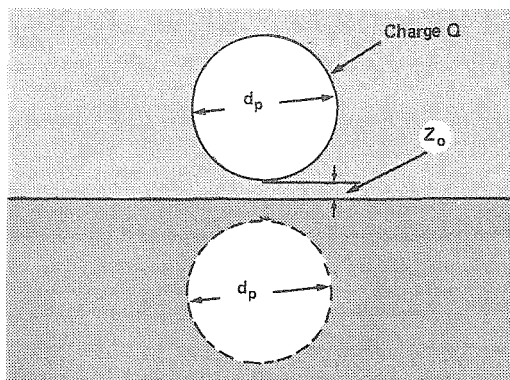
the van der Waals force (only if the Hamaker constant is of the order of  $< 1$  eV).

The other electrostatic interaction occurs due to the electric charge on particle or the substrate surface.

The Coulomb interaction of the charge particle resting on a surface is equivalent to an interaction between the particle and its "image" as shown in Figure 3, resulting in an adhesive force:

$$F_{Ad} = \frac{Q^2}{6(d_p + Z_0)^2}.$$

It should be noted that the charge on particles contacting a surface will change



**FIGURE 3.** Electrostatic interaction between a charged particle and its "image."

with time due to leakage. In general, both types of electrical interactions are important for polymeric materials where the charge leakage is very slow or the van der Waals constant is less than about 1 eV.

### Adhesion Due to Capillary Condensation

Condensation of water vapor can take place in the gap between bodies on contact due to air humidity as shown in Figure 4. The meniscus that is formed draws the bodies together due to surface tension and reduces the pressure of the liquid. The two effects cause an attractive force:

$$F_c = F_{LV} + F_p,$$

where  $F_c$  is the total force due to the presence of water,  $F_{LV}$  is the force caused by the surface tension, and  $F_p$  is the Laplace or capillary pressure. Thus,

$$F_c = 4\pi R\gamma_{LV}\sin\alpha\sin(\theta + \alpha) + 4\pi R\gamma_{LV}\cos\theta,$$

where  $\theta$  is the contact angle. Fisher and Israelachvili (1981) argued that the angle  $\alpha$  is usually very small, and the first term is not very significant.

For wetting liquids,  $\cos\theta \rightarrow 1$  and

$$F_c = 4\pi R\gamma_{LV} \text{ or } 2\pi d_p\gamma_{LV}.$$

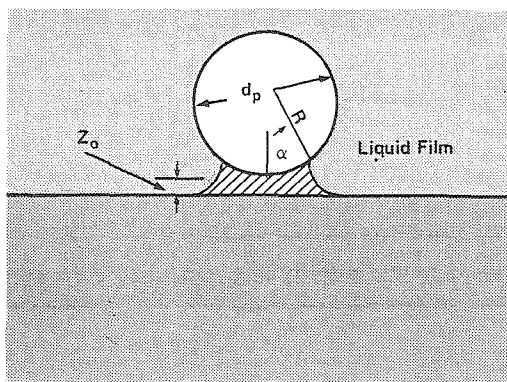


FIGURE 4. Capillary force.

For water,  $\gamma_{LV} = 72$  dyn-cm; and for a  $1\text{-}\mu\text{m}$  particle,

$$F \cong 4.2 \times 10^{-2} \text{ dyn},$$

which is significant in comparison with the van der Waals forces.

Liquid film at the particle-surface interface may be caused by condensation of vapors of common liquids such as water and solvents. The condensation occurs even if the bulk vapor phase is undersaturated, because negative curvature exists in the particle surface contact area. The Kelvin equation states that the vapor pressure in equilibrium with a curved surface is related to surface tension and curvature. Water vapor can begin to condense at a 65–70% level of the equilibrium vapor pressure.

Liquid film may also remain in contact if the surface and particles were originally immersed in a liquid and then dried off. Bhattacharya and Mittal (1978) show that baking for over 24 hr did not reduce adhesion. This may also be attributable to presence of crystallized impurities.

### Double-Layer Repulsion Forces

When particles are immersed in an electrolyte solution, any charge on the particles will attract a layer of ions of the opposite sign. These ions will in turn attract ions of oppo-

site polarity in a diffuse layer. The suspension as a whole will be electrically neutral. The net result is that a potential gradient is established, as shown in Figure 5. This electrical phenomenon is characterized by the measurement of the “zeta potential,  $\zeta$ ” by electrophoretic-mobility measurements and is the potential approximately at the fluid-shear layer.

The origin of charge on particles may be natural or due to adsorption of ions. Polyvalent electrolytes may be used to enhance the magnitude of zeta potential. The repulsive energy between two particles is given by (Hogg et al., 1966):

$$V_R = \frac{\epsilon d p_1 d p_2}{2(a_{dp_1} + a_{dp_2})} \left\{ \Psi_{01}^2 + \Psi_{02}^2 - \Delta\Psi_R(\Psi_{01} + \Psi_{02}) \right. \\ \left. \cdot \left( \frac{|2\Psi_{01}\Psi_{02} - \Delta\Psi_R(\Psi_{01} + \Psi_{02})|}{\Psi_{01}^2 + \Psi_{02}^2 - \Delta\Psi_R(\Psi_{01} + \Psi_{02})} \right) \right. \\ \left. \cdot \ln \frac{1 + e^{-\hat{\kappa}s}}{1 - e^{-\hat{\kappa}s}} + \ln 1 - e^{-2\hat{\kappa}s} \right\},$$

where

$d p_1, d p_2$  = diameters of particles;

$\epsilon$  = dielectric constant;

$\hat{\kappa}^{-1}$  = thickness of the double layer and is inversely proportional to the square root of the ionic strength of the solution;

$\Psi_0$  = surface potential  $\cong \zeta$ , “zeta potential”;

$$\Delta\Psi_R = \Psi_R + \frac{4\pi}{\epsilon k^2} \sum_i z_i e n_{i0} e^{-z_i e x_R / kT};$$

$\Psi_R$  = reference potential;

$z_i$  = volume of  $i^{\text{th}}$  species;

$n_i$  = number of molecules of the  $i^{\text{th}}$  species adsorbed on particle;

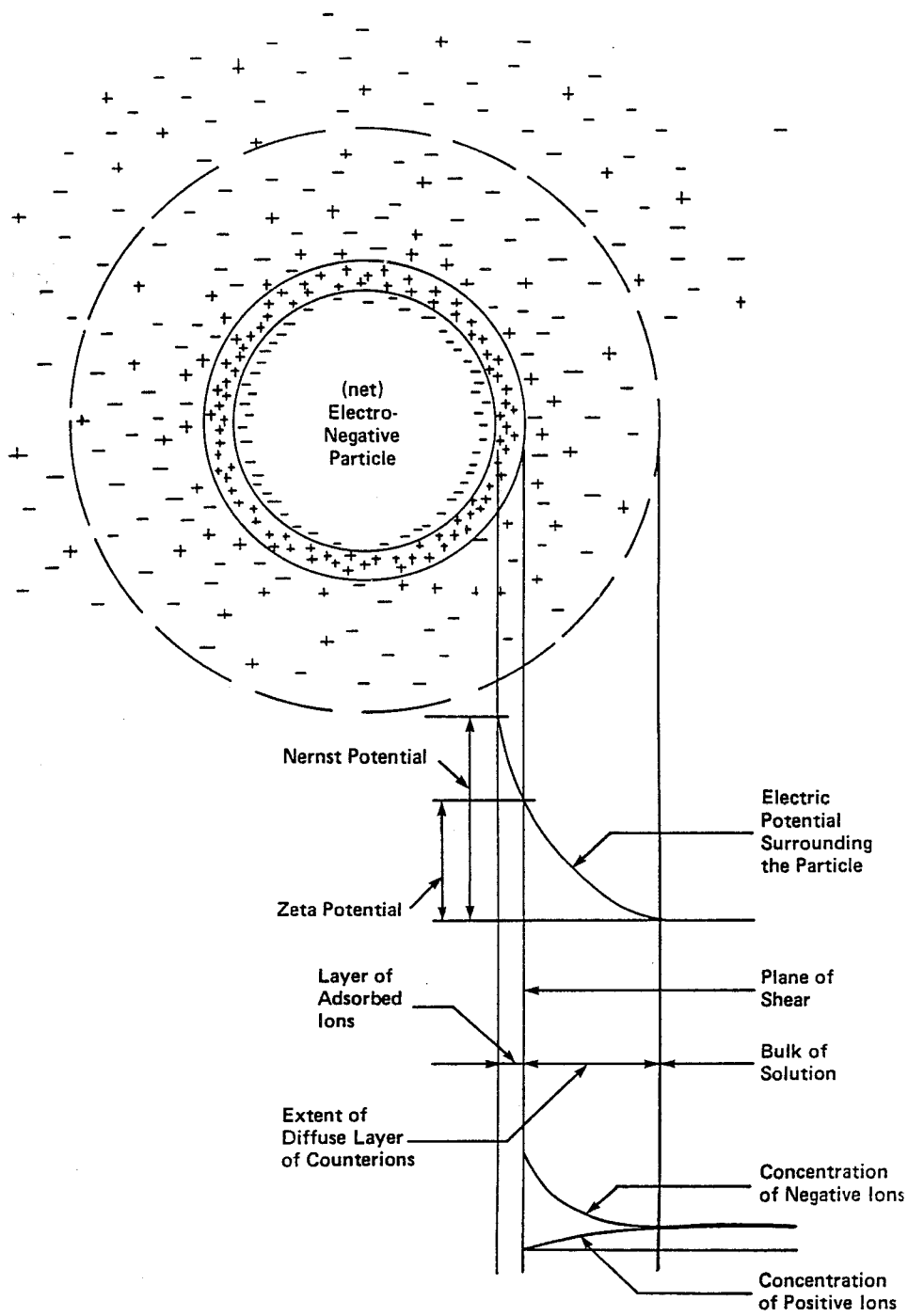
$k$  = Boltzmann constant; and

$s$  = distance of minimum separation

$T$  = absolute temperature;

and the repulsion force is given by:

$$F_R = \left. \frac{dV_R}{dz} \right|_{z_0}.$$



**FIGURE 5.** Electrostatic double layer around a particle.

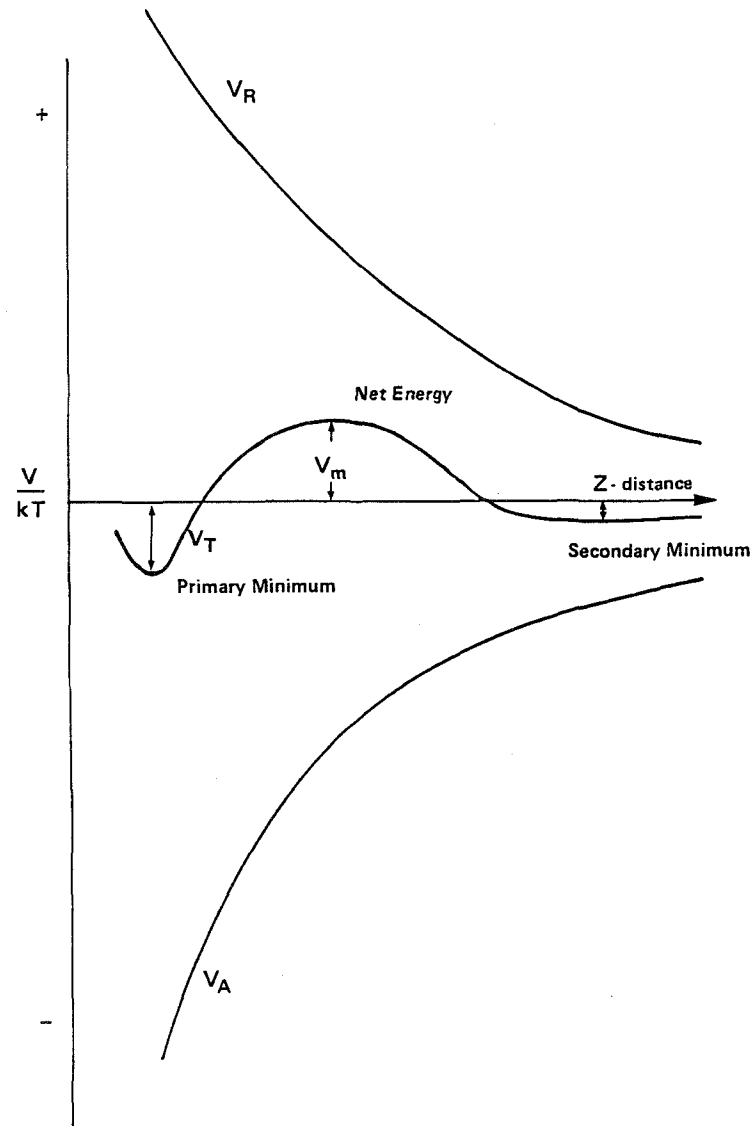
The net interaction energy is schematically shown in Figure 6 as a sum of the attractive and repulsive energy. A secondary minimum and a barrier  $V_m$  in energy is caused and prevents close approach of particles to the surface. This effect leads to very weak adhesion. The primary minimum from van der Waals interaction occurs at about

4–10 Å, whereas the secondary minimum usually occurs at 30–50 Å, away from the particle surface.

Acid–Base Interactions

In addition to the van der Waals dispersion forces, acid–base interactions also play a significant role in adhesion of solid surfaces. Fowkes (1982) and Fowkes et al. (1982) show that adhesion of polymers is significantly controlled by the acidic or basic nature of

FIGURE 6. Interaction energies between particle and surface.



the surfaces. If  $S$  is the number of acid–base sites per unit area and  $-\Delta H^{a-b}$  is the enthalpy of acid–base interactions, the work of adhesion  $W_{1-2}^{a-b}$  attributable to the interactions is given by:

$$W_{1-2}^{a-b} = S\Delta H^{a-b}/N$$

where  $N$  is the Avogadro's number. The interaction enthalpy is obtained from

$$-\Delta H^{a-b} = C_A C_B + E_A E_B$$

where  $C$  and  $E$  constants are determined by measuring the work of adhesion with simple organic acids of known  $C$  and  $E$  values.

### MEASUREMENT OF ADHESION

If several identical particles are dispersed separately upon a substrate, the force required to remove each one will not be the same. It is very common to relate adhesion force using the ratio of the number of particles detached under the influence of a specific force to the initial number on a substrate. A value termed the “adhesion number” is expressed as the ratio of the number of particles remaining on a surface after the application of force to the number initially there. In estimating the force, we realize the existence of a force under which the majority is removed. Kordecki and Orr (1960) and Zimon (1969) show that it is better to estimate the force as being that value at which 50% by number are removed under the specific conditions and measuring method used in the experiment. This is now accepted as being the better method of relating adhesion measurements.

Several methods that have been used to measure particles were devised for particles larger than  $1.0\ \mu\text{m}$ . Zimon (19679) and Corn (1966) have reviewed these extensively.

The following experimental methods have been used to measure the adhesion force of single particles on surfaces:

1. varying the slope of a surface;
2. microbalance technique;
3. pendulum method;

4. centrifuge method;
5. aerodynamic and hydrodynamic method; and
6. vibration method.

Of these, only the latter three are useful for micrometer-sized particles. A summary of the range of applicability is shown in Table 5.

Very limited data on the adhesion force between micrometer-sized particles are available due to the experimental difficulties. Due to the high surface area in relation to the mass of submicrometer particles, the removal force cannot be applied without pushing experimental techniques to the limit. In addition, examination of the fine particles on the substrates is difficult without electron microscopy.

The centrifugal, hydrodynamic, and vibrational techniques are most promising for adhesion measurement. Kordecki et al. (1959) used a centrifuge in studies of the adhesion of particles to a flat surface. Size distribution of the particles initially sprinkled on a slide and the size distribution of those remaining after subsection in discrete steps to successively higher fields of force were measured. The maximum acceleration applied was in excess of  $2000g$ . At maximum acceleration, nearly all of the large particles and a significant fraction of the small particles were removed.

Böhme et al. (1962, 1964a, b, 1965) used an ultracentrifuge capable of producing forces in excess of  $10^6 g$ . They compared the “percentage of particles adhering” versus “applied force (dynes)” and found that the variation of force with particle size was small. The larger acceleration required for the small particles is a consequence of their small mass. Also, these authors have gathered some data on the influence of surface composition and texture on the adhesion of particles to the surface.

Visser (1970) used a hydrodynamic method to measure the force of adhesion between submicron carbon black ( $0.2\text{-}\mu\text{m}$  di-

**TABLE 5.** Summary of Techniques for Adhesion Measurement of Micrometer-Size Particles,  $F = m \cdot a$

Technique	Principle	Parameters	Maximum acceleration (g's)	$F$ (1 $\mu\text{m}$ , 1.0 s · g.) (dyn)
Centrifuge		75,000 rpm (commercial)	$5 \times 10^5$	$3 \times 10^{-4}$
		30,000 rpm (special)	$10^6$	$6 \times 10^{-4}$
Vibration		kHz	$10^5$	$6 \times 10^{-5}$
		MHz	$10^6$	$6 \times 10^{-4}$
Hydrodynamic				
		1,000 rpm	—	$9 \times 10^{-6a}$
		8,000 rpm (concentric cylinders)	—	$2.26 \times 10^{-4a}$
$F_{\text{HYD}} = C_d \cdot S \cdot \frac{v^2}{2} (\rho_p - \rho_l)$				

<sup>a</sup> Visser (1970).

ameter) and cellophane substrates in rotating concentric cylinders. The hydrodynamic force,  $F_{\text{HYD}}$ , is given by:

$$F_{\text{HYD}} = 0.0115N^{3/2}r^2 \text{ dyn},$$

where  $N$  = rpm and  $r$  = particle radius (cm). Speeds up to 8000 rpm were achieved.

Deryagin and Zimon (1961) used a vibrational method to produce accelerations of the order of  $10^4$  g. With the availability of up to several megahertz frequencies, accelerations of the order of  $10^6$  g are possible. Mullins and Ranade (1985) used an ultrasonic horn to study adhesion of micrometer-sized metal flakes.

With the availability of high-frequency transducers, vibrational technique indicates promise for adhesion measurement of sub-micrometer sizes. However, violent cavitation in liquid media at high frequencies may cause problems due to material erosion. Use of high pressures may extend the range of

applications as indicated by Davies et al. (1977).

**RANGE OF ADHESION FORCES AND REMOVAL MECHANISMS**

Adhesion of micrometer-sized and smaller particles to surfaces in air vacuum is very strong, and cleaning of surfaces is difficult. Environmental factors such as relative humidity also have an effect on particle adhesion.

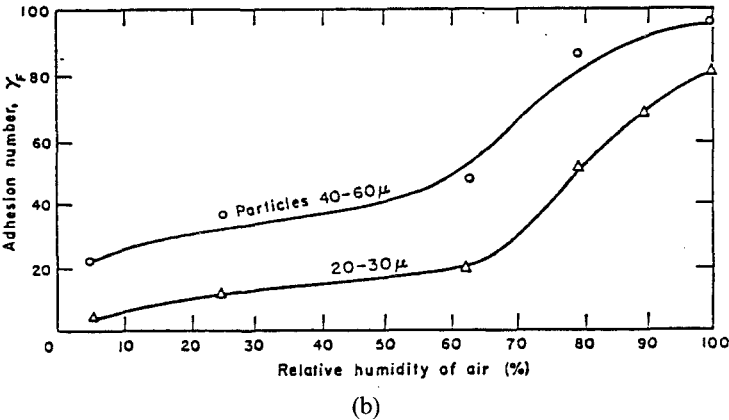
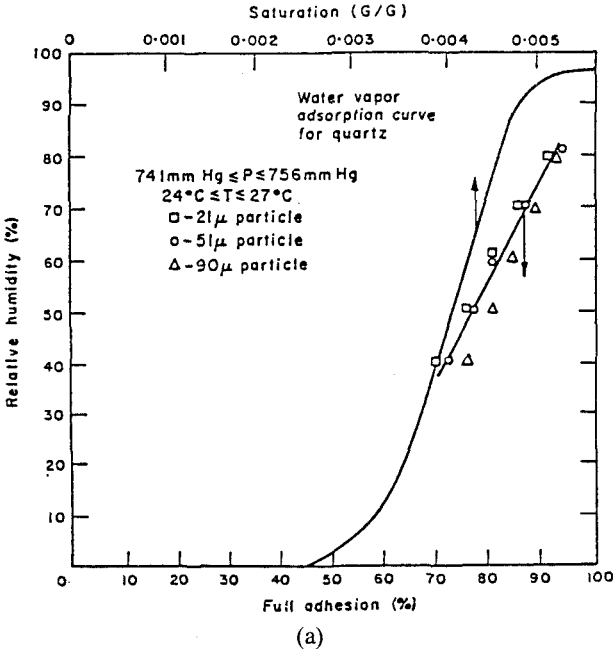
Kordecki and Orr (1960) presented data on particle adhesion as a function of relative humidity. Force of adhesion generally increased with increasing humidity. Capillary condensation at the particle-surface contact region can occur at relative humidities of about 60–70%. Corn (1966) summarized his and other workers' results to emphasize the effect of humidity on adhesion. Two exam-

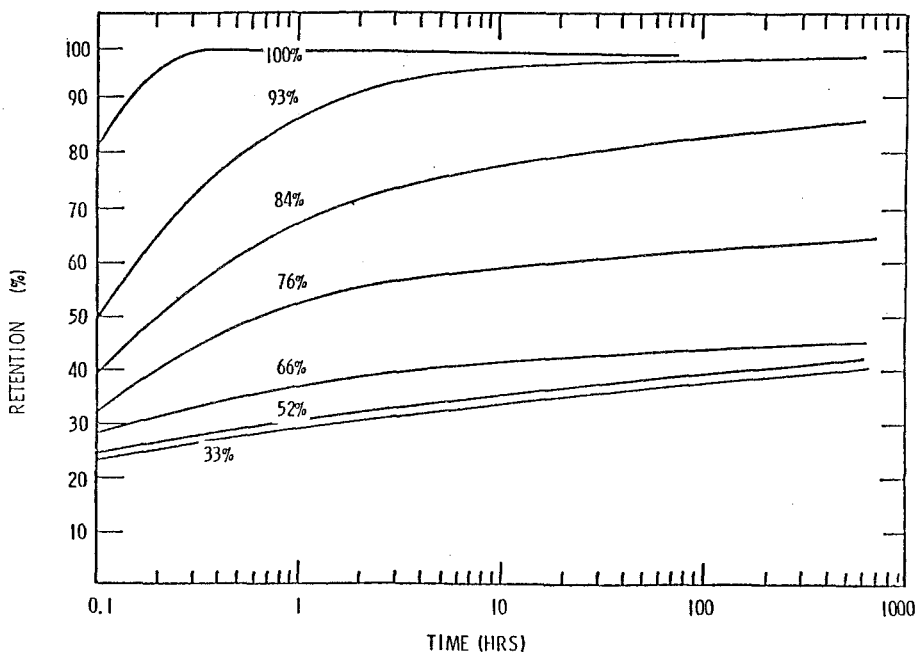
ples are shown in Figure 7. Whitfield (1979) showed that at relative humidities above 50%, adhesion of ambient particles to surfaces drastically increases, as summarized in Figure 8. The plot shows the percentage of retention after being subjected to a nitrogen stream blowoff for periods of up to 100 hr.

Bhattacharya and Mittal (1978) studied adhesion and removal of glass microbeads smaller than 5  $\mu\text{m}$  on a silicon wafer. The capillary force resulting from a liquid be-

tween the particles and surface was very strong. The capillary force persisted, even after baking for up to 24 hr. This study indicates that the capillary force is of great importance, even at relative humidities less than 50% if a liquid film is caused by excur-

**FIGURE 7.** Effect of relative humidity on particle adhesion (Corn, 1966): (a) adhesion of quartz particles to Pyrex; (b) adhesion of glass particles to quartz.





**FIGURE 8.** Effect of relative humidity on particle retention (Whitfield, 1979).

sion through high-humidity atmospheres or prior immersion in a liquid.

Use of a liquid, rather than air or vacuum as the surrounding medium, facilitates particle removal. Two features involving liquid media may be exploited. First, the van der Waals interactions are one to two orders of magnitude smaller. In addition, surface-active agents may be employed to take advantage of the double-layer repulsion forces, as shown in Figure 9 taken from Clayfield and Lumb (1970).

In Figure 9, removal of several different carbon blacks on stainless-steel powder grains is shown against the surfactant concentration. The three top curves represent polar carbon blacks, and the lower curve represents graphitized blacks with nonpolar surfaces. The adhesion for the polar particles was lower than for the nonpolar black, and the effect of surfactant concentration on removal was evident only for the polar carbons. These results suggest that double-layer re-

pulsion caused by the presence of the surfactant would not completely explain the removal behavior. Steric repulsion must be responsible for holding the particles at or near the secondary minimum for the polar carbons. Surfactants are effectively adsorbed on such particles. The graphitized carbons, on the other hand, are probably close to the primary minimum, and the surfactant is not effectively adsorbed.

Kuo and Matijević (1980) and Kallay and Matijević (1981) studied removal of 0.17- $\mu\text{m}$  hematite particles from stainless steel and show that the ionic strength of pH of the aqueous solution of sodium dodecyl sulfate and ethylenediaminetetraacetic acid were important variables. The removal was highest at around a pH of 11.5. Increasing temperature of the solution also increased removal over the 25 to 80°C range studied. A similar effect of temperature was reported by Ranade et al. (1986).

Brandreth and Johnson (1979) describe particle removal from surfaces by several common solvents, such as alcohol mixtures with fluorocarbons. The action was not by dissolution by solvents but by reduced

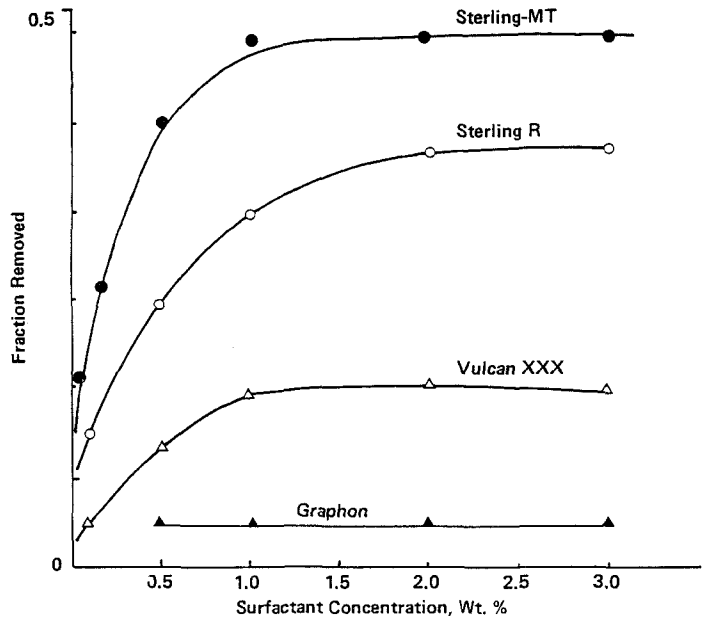


FIGURE 9. Effect of surfactants on particle removal (Clayfield and Lumb, 1970).

molecular interaction as well as adsorption on the particle and substrate, changing the original molecular interactions. Several types of Freons were shown to be very effective in particle removal at relatively low accelerations.

The processes available for particle removal incorporate the same mechanical actions indicated for adhesion-measurement techniques. The acceleration may be provided by agitation, centrifugation, vibration, or by aerodynamic or hydrodynamic drag.

Zimon (1969) discussed the role of drag on particle removal by air as well as water flow. The force that is required for detachment of small particles is expressed by:

$$F \geq \mu F_{Ad},$$

where  $\mu$  is the friction coefficient. The drag force,  $F$ , is given by:

$$F = C_d S \frac{v^2}{2} (\rho_p - \rho_f),$$

where  $C_d$  is the drag coefficient,  $v$  is fluid velocity, and  $\rho_p$  and  $\rho_f$  are densities of particle and fluid, respectively. For linear distribution of velocity in the boundary layer on

the substrate, the “Stokes’ Law” gives:

$$F = \frac{3\pi\eta v_0 d_p^2}{2\delta}$$

where  $\delta$  is the boundary-layer thickness, and  $v_0$  is the average fluid velocity. The boundary-layer thickness is usually sufficiently larger than the particles.

Air or nitrogen blowoff guns are usually effective in removing large particles ( $> 10 \mu\text{m}$ ) from the surface but ineffective in removing smaller particles. Liquid jets are also employed in cleaning surfaces. Stowers (1978) applied a high-pressure 6.9-MPa liquid spraying technique using Freon TF solvent to remove  $\text{Al}_2\text{O}_3$  particles larger than  $5 \mu\text{m}$  in size from glass and a metallic surface. Comparison was also made with other removal methods such as compressed gas jets and ultrasonic cleaning also using Freon TF as the medium. Close to 99% removal by the high-pressure spray was reported, compared to  $\sim 60\%$  for compressed gas and  $\sim 90\%$  for

ultrasonic cleaning. The removal values were based on the initial particles number on the surface, which was degreased and irradiated. The degreasing and irradiation removed about 33% of the particles before the ultrasonic or the high-pressure jet treatments. The true removal efficiency numbers may be significantly lower than reported. The paper also contains removal efficiency values for  $\geq 1\text{-}\mu\text{m}$ -sized particles. However, no discussion of how these values were obtained is given in the paper. As expected, larger particles are removed better, indicating that the technique may be effective for larger particles only without the use of elevated temperature or use of surfactants.

Ultrasonic devices operating at around 20 kHz have been used for effective cleaning of surfaces in liquids. The mechanism of the action of ultrasound on a particle or agglomerate is not fully understood. In all types of particle processing systems, it has been reported that some form of cavitation is desirable to attain dispersion by ultrasonic means. Particle dispersion is thought to occur by the action of a collapsing cavitation bubble at the agglomerate interface. The mechanical disturbances that are caused by high-intensity sound waves produce pressure fluctuations, above and below their ambient pressure. In the reduced-pressure cycle, bubbles tend to form and grow; whereas in the increased-pressure cycle, bubble growth stops, and bubbles either oscillate or collapse. At the collapsing bubble interface, high enough energy is released in a highly localized region to overcome interparticle forces in agglomerate structures. These conditions involving bubble collapse or bubble oscillation have been termed transient and stable cavitation. In a normal cavitating liquid, both are present; and for dispersion effects to be the strongest, transient cavitation has to be optimized.

Brodov et al. (1970) reported that during precipitation of a particulate solid, the particle size decreased from  $> 1\text{ }\mu\text{m}$  without ultrasound to  $< 0.3\text{ }\mu\text{m}$  in an ultrasonic field

under atmospheric pressure. At a pressure of 24 atm, the particle size further decreased to  $0.08\text{--}0.1\text{ }\mu\text{m}$ . Holl (1973) also noted that the dispersion of submicrometer particles was promoted at high pressures.

Satoh and Yamane (1972) fractionated a volcanic ash with the use of ultrasound. Most of the inorganic and organic complexes were successfully separated from the aggregates easily. The clay minerals were less than  $2\text{ }\mu\text{m}$  in diameter, and other minerals containing Fe oxides and sand were less than  $0.5\text{ }\mu\text{m}$  in diameter.

Kaiser (1973) found that ultrasonics were useful in the separation of submicron carbon, calcium fluoride, and other compounds and found that separation in fluorinated hydrocarbons of low surface tension was very efficient.

Reports of other uses of ultrasound for dispersion were given by Agabalyants et al. (1970) and by Lowe and Parasher (1971), who studied the dispersion of clay and soils, respectively.

Various types of ultrasonic devices were devised for the separation of submicrometer particles. Hislop (1970) reported on two devices that utilized the ultrasonic energy most efficiently.

Davies et al. (1977) designed and constructed a batch device for the separation of inorganic metal oxides and atmospheric aerosols from filters. This device was capable of operating at various power, pressure, temperature, and time conditions. Operation in aqueous sodium pyrophosphate solutions was limited to low power and pressure due to erosion difficulties, but operation in fluorocarbons (e.g., 1% Krytox 157 in Freon E-3 at 100 psi and 100 W) was most effective in separating submicron particulates under conditions of negligible erosion.

Schwartzman et al. (1985) described a "megasonic" cleaning system operating at frequencies in 850 to 900 kHz. It was claimed that in contrast to ultrasonics, the higher frequencies produce a cleaning action greater than the cavitation encountered in ultrasonic

devices. A high-pressure wave is suggested as the mechanism for particle removal. The device was shown to be effective in removing 0.3- $\mu\text{m}$  particles using a hydrogen peroxide solution. Water alone did not work as well. Although a surfactant solution (Triton-X) worked better, it did not work as well as did the peroxide solution.

The qualitative hypothesis for the cleaning action does not explain the results reported by Schwartzman et al. (1985), who used different cleaning fluids. Further work is necessary to determine best conditions for particle removal.

A proper choice of the cleaning system, the cleaning fluid, and the potential use of surfactants is not available at this stage, and the need for a systematic study of a cleaning mechanism is urgently needed.

## SUMMARY

Although significant theoretical developments have been made in understanding particle adhesion, quantitative estimation is still elusive. Uncertainties are encountered in defining the true contact area, distance of separation, and deformation of particle and substrates. Molecular and electrical forces, together with environmental conditions such as humidity and medium, determine adhesion of contaminant particles on surfaces. Removal of particles smaller than several micrometers is extremely difficult due to the high acceleration required. Considerable research will be required to measure sub-micrometer-particle adhesion and develop cleaning techniques based on the use of medium effect (such as the negative Hamaker constant), the use of surfactants, and methods for providing sufficient acceleration.

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# **EXHIBIT DX46**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS

# Bair Hugger Blanket





# See-Through Drape Over Patient's Head



# Clear Plastic Drape – Under Right Leg and on to the Left Leg



# Clear Plastic Drape Above Waist



# Clear Plastic Drapes Above and Below Waist



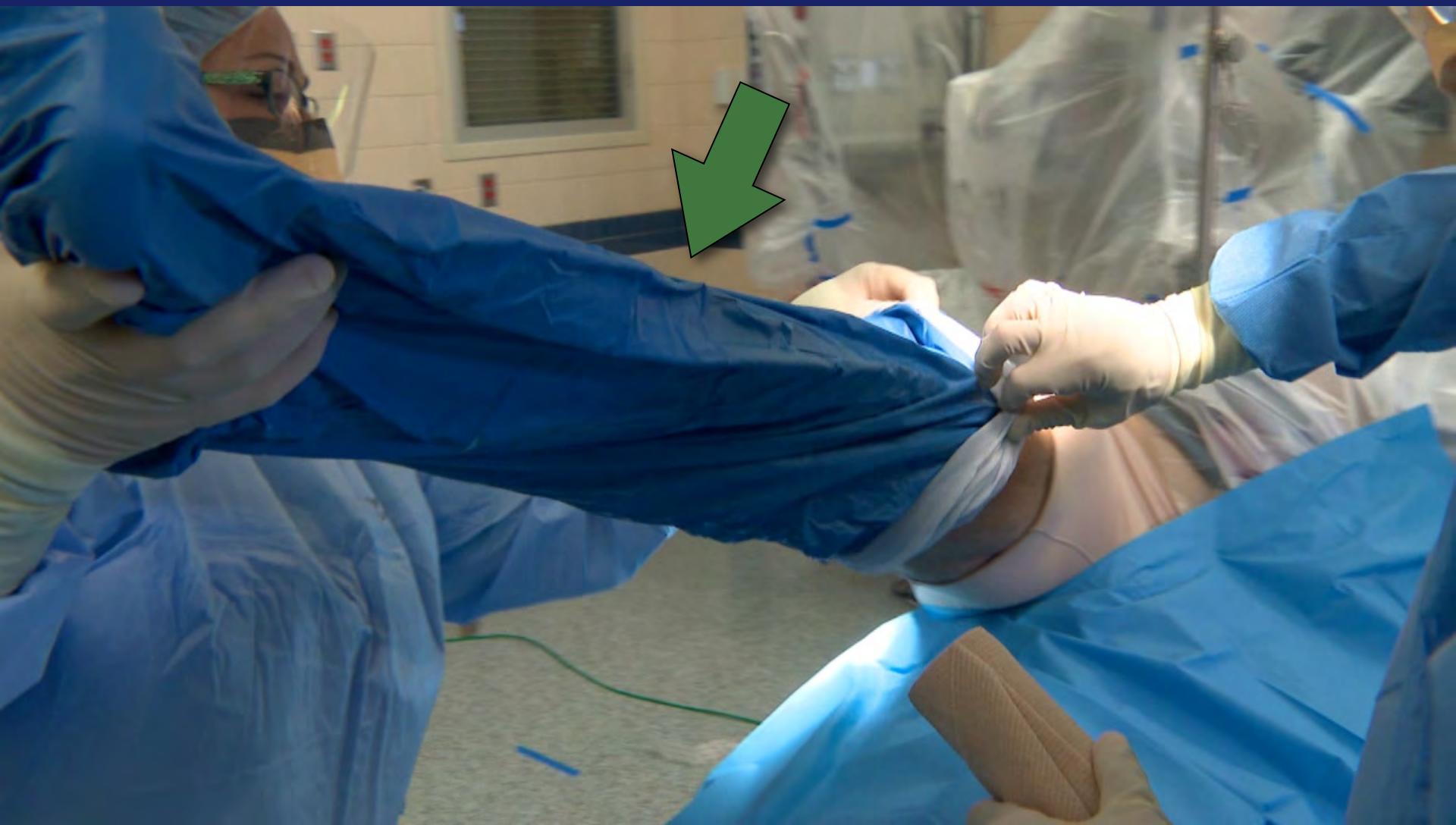
# Sterile Drape Over Clear Plastic Drape



# Sterile Split Sheet – Over Sterile Drape and Clear Plastic Drape



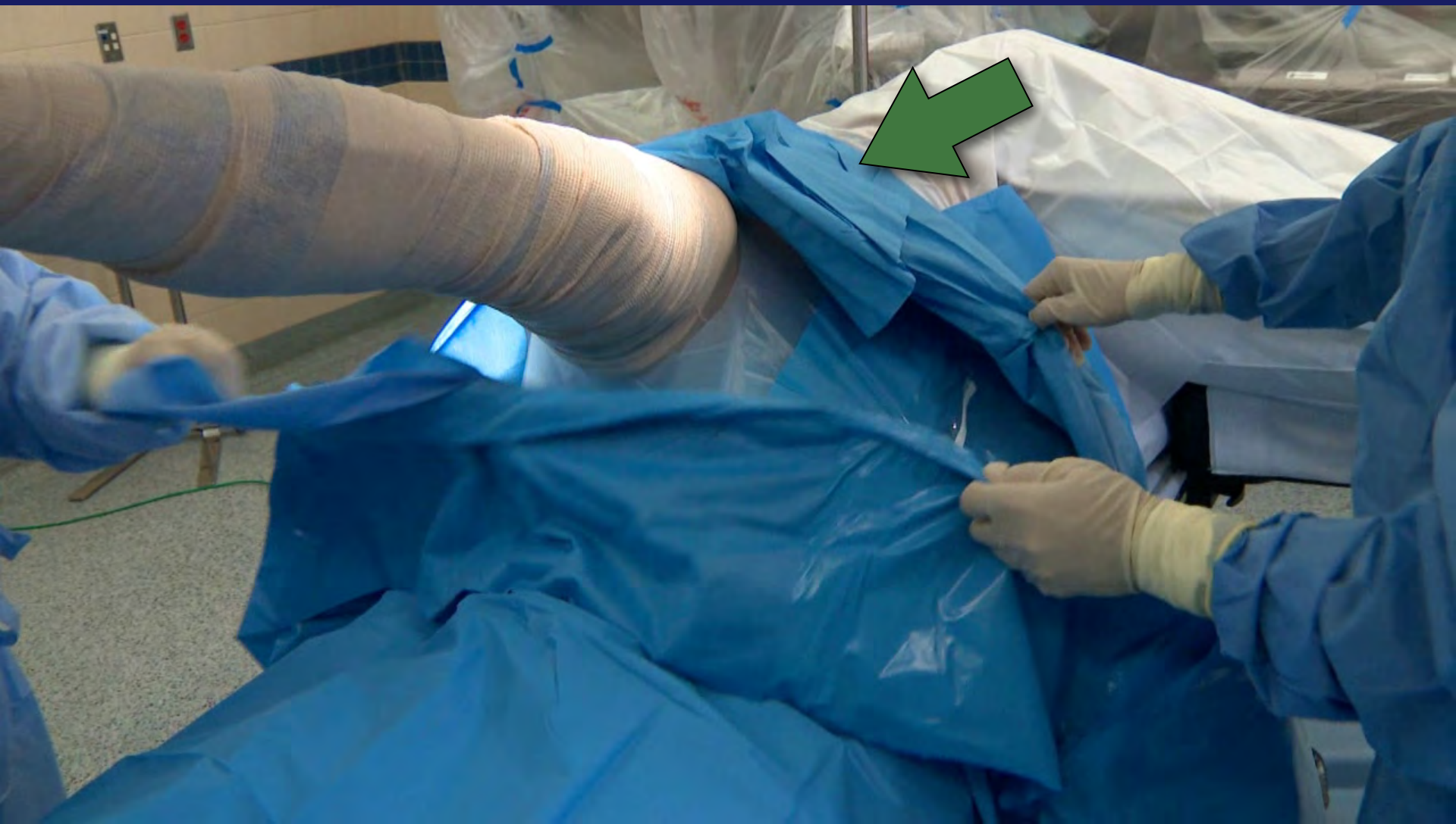
# Sterile Stocking (Stockinette)



# Sterile Drape (Coban) Over Sterile Stocking (Stockinette)



# Sterile Hip Drape



# Sterile Hip Drape Used as Anesthesia Screen



# Sterile Hip Drape Used as Anesthesia Screen

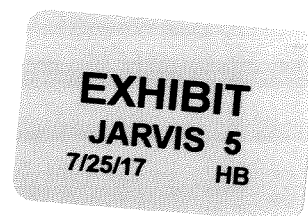


# Sterile Drape (Ioban) Placed Directly Over Incision Site



# **EXHIBIT DX47**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS



## SPECIAL ARTICLES

# Guideline for Prevention of Surgical Site Infection, 1999

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## EXECUTIVE SUMMARY

The "Guideline for Prevention of Surgical Site Infection, 1999" presents the Centers for Disease Control and Prevention (CDC)'s recommendations for the prevention of surgical site infections (SSIs), formerly called surgical wound infections. This two-part guideline updates and replaces previous guidelines.<sup>1,2</sup>

Part I, "Surgical Site Infection: An Overview," describes the epidemiology, definitions, microbiology, pathogenesis, and surveillance of SSIs. Included is a detailed discussion of the pre-, intra-, and postoperative issues relevant to SSI genesis.

Part II, "Recommendations for Prevention of Surgical Site Infection," represents the consensus of the Hospital Infection Control Practices Advisory Committee (HICPAC) regarding strategies for the prevention of SSIs.<sup>3</sup> Whenever possible, the recommendations in Part II are based on data from well-designed scientific studies. However, there are a limited number of studies that clearly validate risk factors and prevention measures for SSI. By necessity, available studies have often been conducted in narrowly defined patient populations or for specific kinds of operations, making generalization of their findings to all specialties and types of operations potentially problematic. This is especially true regarding the implementation of SSI prevention measures. Finally, some of the infection control practices routinely used by surgical teams cannot be rigorously studied for ethical or logistical reasons (e.g., wearing vs not wearing gloves). Thus, some of the

recommendations in Part II are based on a strong theoretical rationale and suggestive evidence in the absence of confirmatory scientific knowledge.

It has been estimated that approximately 75% of all operations in the United States will be performed in "ambulatory," "same-day," or "outpatient" operating rooms by the turn of the century.<sup>4</sup> In recommending various SSI prevention methods, this document makes no distinction between surgical care delivered in such settings and that provided in conventional inpatient operating rooms. This document is primarily intended for use by surgeons, operating room nurses, postoperative inpatient and clinic nurses, infection control professionals, anesthesiologists, healthcare epidemiologists, and other personnel directly responsible for the prevention of nosocomial infections.

This document does *not*:

- Specifically address issues unique to burns, trauma, transplant procedures, or transmission of blood-borne pathogens from healthcare worker to patient, nor does it specifically address details of SSI prevention in pediatric surgical practice. It has been recently shown in a multicenter study of pediatric surgical patients that characteristics related to the operations are more important than those related to the physiologic status of the patients.<sup>5</sup> In general, all SSI prevention measures effective in adult surgical care are indicated in pediatric surgical care.
- Specifically address procedures performed outside of the operating room (e.g., endoscopic proce-

dures), nor does it provide guidance for infection prevention for invasive procedures such as cardiac catheterization or interventional radiology. Nonetheless, it is likely that many SSI prevention strategies also could be applied or adapted to reduce infectious complications associated with these procedures.

- Specifically recommend SSI prevention methods unique to minimally invasive operations (i.e., laparoscopic surgery). Available SSI surveillance data indicate that laparoscopic operations generally

have a lower or comparable SSI risk when contrasted to open operations.<sup>6-11</sup> SSI prevention measures applicable in open operations (e.g., open cholecystectomy) are indicated for their laparoscopic counterparts (e.g., laparoscopic cholecystectomy).

- Recommend specific antiseptic agents for patient preoperative skin preparations or for healthcare worker hand/forearm antisepsis. Hospitals should choose from products recommended for these activities in the latest Food and Drug Administration (FDA) monograph.<sup>12</sup>

## I. Surgical Site Infection (SSI): An Overview

### A. INTRODUCTION

Before the mid-19th century, surgical patients commonly developed postoperative "irritative fever," followed by purulent drainage from their incisions, overwhelming sepsis, and often death. It was not until the late 1860s, after Joseph Lister introduced the principles of antisepsis, that postoperative infectious morbidity decreased substantially. Lister's work radically changed surgery from an activity associated with infection and death to a discipline that could eliminate suffering and prolong life.

Currently, in the United States alone, an estimated 27 million surgical procedures are performed each year.<sup>13</sup> The CDC's National Nosocomial Infections Surveillance (NNIS) system, established in 1970, monitors reported trends in nosocomial infections in U.S. acute-care hospitals. Based on NNIS system reports, SSIs are the third most frequently reported nosocomial infection, accounting for 14% to 16% of all nosocomial infections among hospitalized patients.<sup>14</sup> During 1986 to 1996, hospitals conducting SSI surveillance in the NNIS system reported 15,523 SSIs following 593,344 operations (CDC, unpublished data). Among surgical patients, SSIs were the most common nosocomial infection, accounting for 38% of all such infections. Of these SSIs, two thirds were confined to the incision, and one third involved organs or spaces accessed during the operation. When surgical patients with nosocomial SSI died, 77% of the deaths were reported to be related to the infection, and the majority (93%) were serious infections involving organs or spaces accessed during the operation.

In 1980, Cruse estimated that an SSI increased a patient's hospital stay by approximately 10 days and cost an additional \$2,000.<sup>15,16</sup> A 1992 analysis showed that each SSI resulted in 7.3 additional postoperative hospital days, adding \$3,152 in extra charges.<sup>17</sup> Other studies corroborate that increased length of hospital stay and cost are associated with SSIs.<sup>18,19</sup> Deep SSIs

involving organs or spaces, as compared to SSIs confined to the incision, are associated with even greater increases in hospital stays and costs.<sup>20,21</sup>

Advances in infection control practices include improved operating room ventilation, sterilization methods, barriers, surgical technique, and availability of antimicrobial prophylaxis. Despite these activities, SSIs remain a substantial cause of morbidity and mortality among hospitalized patients. This may be partially explained by the emergence of antimicrobial-resistant pathogens and the increased numbers of surgical patients who are elderly and/or have a wide variety of chronic, debilitating, or immunocompromising underlying diseases. There also are increased numbers of prosthetic implant and organ transplant operations performed. Thus, to reduce the risk of SSI, a systematic but realistic approach must be applied with the awareness that this risk is influenced by characteristics of the patient, operation, personnel, and hospital.

### B. KEY TERMS USED IN THE GUIDELINE

#### 1. Criteria for defining SSIs

The identification of SSI involves interpretation of clinical and laboratory findings, and it is crucial that a surveillance program use definitions that are consistent and standardized; otherwise, inaccurate or uninterpretable SSI rates will be computed and reported. The CDC's NNIS system has developed standardized surveillance criteria for defining SSIs (Table 1).<sup>22</sup> By these criteria, SSIs are classified as being either incisional or organ/space. Incisional SSIs are further divided into those involving only skin and subcutaneous tissue (superficial incisional SSI) and those involving deeper soft tissues of the incision (deep incisional SSI). Organ/space SSIs involve any part of the anatomy (e.g., organ or space) other than incised body wall layers, that

**Table 1.** Criteria for Defining a Surgical Site Infection (SSI)\***Superficial Incisional SSI**

Infection occurs within 30 days after the operation *and* infection involves only skin or subcutaneous tissue of the incision *and* at least *one* of the following:

1. Purulent drainage, with or without laboratory confirmation, from the superficial incision.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat *and* superficial incision is deliberately opened by surgeon, *unless* incision is culture-negative.
4. Diagnosis of superficial incisional SSI by the surgeon or attending physician.

Do *not* report the following conditions as SSI:

1. Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration).
2. Infection of an episiotomy or newborn circumcision site.
3. Infected burn wound.
4. Incisional SSI that extends into the fascial and muscle layers (see deep incisional SSI).

*Note:* Specific criteria are used for identifying infected episiotomy and circumcision sites and burn wounds.<sup>433</sup>

**Deep incisional SSI**

Infection occurs within 30 days after the operation if no implant† is left in place or within 1 year if implant is in place and the infection appears to be related to the operation *and* infection involves deep soft tissues (e.g., fascial and muscle layers) of the incision *and* at least *one* of the following:

1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38°C), localized pain, or tenderness, unless site is culture-negative.
3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

*Notes:*

1. Report infection that involves both superficial and deep incision sites as deep incisional SSI.
2. Report an organ/space SSI that drains through the incision as a deep incisional SSI.

**Organ/space SSI**

Infection occurs within 30 days after the operation if no implant† is left in place or within 1 year if implant is in place and the infection appears to be related to the operation *and* infection involves any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation *and* at least *one* of the following:

1. Purulent drainage from a drain that is placed through a stab wound‡ into the organ/space.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.
3. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of an organ/space SSI by a surgeon or attending physician.

\* Horan TC et al.<sup>22</sup>

†National Nosocomial Infection Surveillance definition: a nonhuman-derived implantable foreign body (e.g., prosthetic heart valve, nonhuman vascular graft, mechanical heart, or hip prosthesis) that is permanently placed in a patient during surgery.

‡If the area around a stab wound becomes infected, it is not an SSI. It is considered a skin or soft tissue infection, depending on its depth.

was opened or manipulated during an operation (Figure). Table 2 lists site-specific classifications used to differentiate organ/space SSIs. For example, in a patient who had an appendectomy and subsequently developed an intra-abdominal abscess not draining through the incision, the infection would be reported as an organ/space SSI at the intra-abdominal site. Failure to use objective criteria to define SSIs has been shown to substantially affect reported SSI rates.<sup>23,24</sup> The CDC NNIS definitions of SSIs have been applied consistently by surveillance and surgical personnel in many settings and currently are a de facto national standard.<sup>22,25</sup>

**2. Operating suite**

A physically separate area that comprises operating rooms and their interconnecting hallways and ancillary work areas such as scrub sink rooms. No distinction is

made between operating suites located in conventional inpatient hospitals and those used for “same-day” surgical care, whether in a hospital or a free-standing facility.

**3. Operating room**

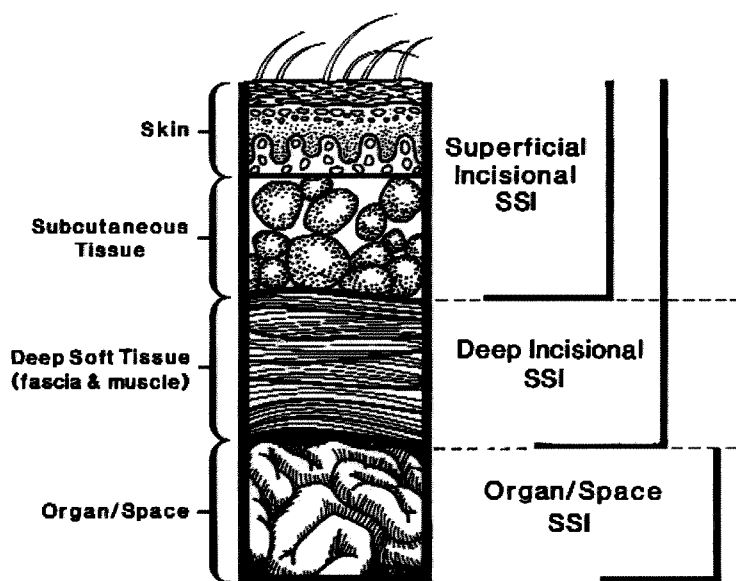
A room in an operating suite where operations are performed.

**4. Surgical personnel**

Any healthcare worker who provides care to surgical patients during the pre-, intra-, or postoperative periods.

**5. Surgical team member**

Any healthcare worker in an operating room during the operation who has a surgical care role. Members of the surgical team may be “scrubbed” or not; scrubbed members have direct contact with the sterile operating field or



**Figure.** Cross-section of abdominal wall depicting CDC classifications of surgical site infection.<sup>22</sup>

sterile instruments or supplies used in the field (refer to "Preoperative Hand/Forearm Antisepsis" section).

### C. MICROBIOLOGY

According to data from the NNIS system, the distribution of pathogens isolated from SSIs has not changed markedly during the last decade (Table 3).<sup>26,27</sup> *Staphylococcus aureus*, coagulase-negative staphylococci, *Enterococcus* spp., and *Escherichia coli* remain the most frequently isolated pathogens. An increasing proportion of SSIs are caused by antimicrobial-resistant pathogens, such as methicillin-resistant *S. aureus* (MRSA),<sup>28,29</sup> or by *Candida albicans*.<sup>30</sup> From 1991 to 1995, the incidence of fungal SSIs among patients at NNIS hospitals increased from 0.1 to 0.3 per 1,000 discharges.<sup>30</sup> The increased proportion of SSIs caused by resistant pathogens and *Candida* spp. may reflect increasing numbers of severely ill and immunocompromised surgical patients and the impact of widespread use of broad-spectrum antimicrobial agents.

Outbreaks or clusters of SSIs have also been caused by unusual pathogens, such as *Rhizopus oryzae*, *Clostridium perfringens*, *Rhodococcus bronchialis*, *Nocardia farcinica*, *Legionella pneumophila* and *Legionella dumoffii*, and *Pseudomonas multivorans*. These rare outbreaks have been traced to contaminated adhesive dressings,<sup>31</sup> elastic bandages,<sup>32</sup> colonized surgical personnel,<sup>33,34</sup> tap water,<sup>35</sup> or contaminated disinfectant solutions.<sup>36</sup> When a cluster of SSIs involves an unusual organism, a formal epidemiologic investigation should be conducted.

### D. PATHOGENESIS

Microbial contamination of the surgical site is a necessary precursor of SSI. The risk of SSI can be conceptualized according to the following relationship<sup>37,38</sup>:

$$\frac{\text{Dose of bacterial contamination} \times \text{virulence}}{\text{Resistance of the host patient}} = \text{Risk of surgical site infection}$$

Quantitatively, it has been shown that if a surgical site is contaminated with  $>10^5$  microorganisms per gram of tissue, the risk of SSI is markedly increased.<sup>39</sup> However, the dose of contaminating microorganisms required to produce infection may be much lower when foreign material is present at the site (i.e., 100 staphylococci per gram of tissue introduced on silk sutures).<sup>40-42</sup>

Microorganisms may contain or produce toxins and other substances that increase their ability to invade a host, produce damage within the host, or survive on or in host tissue. For example, many gram-negative bacteria produce endotoxin, which stimulates cytokine production. In turn, cytokines can trigger the systemic inflammatory response syndrome that sometimes leads to multiple system organ failure.<sup>43-45</sup> One of the most common causes of multiple system organ failure in modern surgical care is intra-abdominal infection.<sup>46,47</sup> Some bacterial surface components, notably polysaccharide capsules, inhibit phagocytosis,<sup>48</sup> a critical and early host defense response to microbial contamination. Certain strains of clostridia and streptococci produce potent exotoxins that disrupt cell membranes or alter cellular metabolism.<sup>49</sup> A variety of microorgan-

**Table 2.** Site-Specific Classifications of Organ/Space Surgical Site Infection\*

Arterial or venous infection	Meningitis or ventriculitis
Breast abscess or mastitis	Myocarditis or pericarditis
Disc space	Oral cavity (mouth, tongue, or gums)
Ear, mastoid	Osteomyelitis
Endocarditis	Other infections of the lower respiratory tract (e.g., abscess or empyema)
Endometritis	Other male or female reproductive tract
Eye, other than conjunctivitis	Sinusitis
Gastrointestinal tract	Spinal abscess without meningitis
Intra-abdominal, not specified elsewhere	Upper respiratory tract
Intracranial, brain abscess or dura	Vaginal cuff
Joint or bursa	
Mediastinitis	

\*Horan TC et al.<sup>22</sup>**Table 3.** Distribution of Pathogens Isolated\* From Surgical Site Infections, National Nosocomial Infections Surveillance System, 1986 to 1996

Pathogen	Percentage of isolates	
	1986-1989 <sup>179</sup> (N=16,727)	1990-1996 <sup>26</sup> (N=17,671)
<i>Staphylococcus aureus</i>	17	20
Coagulase-negative staphylococci	12	14
<i>Enterococcus</i> spp.	13	12
<i>Escherichia coli</i>	10	8
<i>Pseudomonas aeruginosa</i>	8	8
<i>Enterobacter</i> spp.	8	7
<i>Proteus mirabilis</i>	4	3
<i>Klebsiella pneumoniae</i>	3	3
Other <i>Streptococcus</i> spp.	3	3
<i>Candida albicans</i>	2	3
Group D streptococci (non-enterococci)	—	2
Other gram-positive aerobes	—	2
<i>Bacteroides fragilis</i>	—	2

\*Pathogens representing less than 2% of isolates are excluded.

isms, including gram-positive bacteria such as coagulase-negative staphylococci, produce glycocalyx and an associated component called "slime,"<sup>50-55</sup> which physically shields bacteria from phagocytes or inhibits the binding or penetration of antimicrobial agents.<sup>56</sup> Although these and other virulence factors are well defined, their mechanistic relationship to SSI development has not been fully determined.

For most SSIs, the source of pathogens is the endogenous flora of the patient's skin, mucous membranes, or hollow viscera.<sup>57</sup> When mucous membranes or skin is incised, the exposed tissues are at risk for contamination with endogenous flora.<sup>58</sup> These organisms are usually aerobic gram-positive cocci (e.g., staphylococci), but may include fecal flora (e.g., anaerobic bacteria and gram-negative aerobes) when incisions are made near the perineum or groin. When a gastrointestinal organ is opened during an operation and is the source of pathogens, gram-negative bacilli (e.g., *E. coli*), gram-positive organisms (e.g., enterococci), and sometimes anaerobes (e.g., *Bacillus fragilis*) are the typical SSI iso-

lates. Table 4 lists operations and the likely SSI pathogens associated with them. Seeding of the operative site from a distant focus of infection can be another source of SSI pathogens,<sup>59-68</sup> particularly in patients who have a prosthesis or other implant placed during the operation. Such devices provide a nidus for attachment of the organism.<sup>50,69-73</sup>

Exogenous sources of SSI pathogens include surgical personnel (especially members of the surgical team),<sup>74-78</sup> the operating room environment (including air), and all tools, instruments, and materials brought to the sterile field during an operation (refer to "Intraoperative Issues" section). Exogenous flora are primarily aerobes, especially gram-positive organisms (e.g., staphylococci and streptococci). Fungi from endogenous and exogenous sources rarely cause SSIs, and their pathogenesis is not well understood.<sup>79</sup>

## E. RISK AND PREVENTION

The term *risk factor* has a particular meaning in epidemiology and, in the context of SSI pathophysiol-

**Table 4.** Operations, Likely Surgical Site Infection (SSI) Pathogens, and References on Usage of Antimicrobial Prophylaxis\*

Operations	Likely Pathogenst‡	References
Placement of all grafts, prostheses, or implants	<i>Staphylococcus aureus</i> ; coagulase-negative staphylococci	269,282-284,290
Cardiac	<i>Staphylococcus aureus</i> ; coagulase-negative staphylococci	251-253,462,463
Neurosurgery	<i>Staphylococcus aureus</i> ; coagulase-negative staphylococci	241,249,258,259,261, 464,465
Breast	<i>Staphylococcus aureus</i> ; coagulase-negative staphylococci	242,248
Ophthalmic	<i>Staphylococcus aureus</i> ; coagulase-negative staphylococci	466
Limited data: however, commonly used in procedures such as anterior segment resection, vitrectomy, and scleral buckles	staphylococci; streptococci; gram-negative bacilli	
Orthopedic	<i>Staphylococcus aureus</i> ; coagulase-negative staphylococci; gram-negative bacilli	60,243-246,254, 255,467-473
Total joint replacement Closed fractures/use of nails, bone plates, other internal fixation devices Functional repair without implant/device Trauma		
Noncardiac thoracic	<i>Staphylococcus aureus</i> ; coagulase-negative staphylococci	240,247,474,475
Thoracic (lobectomy, pneumonectomy, wedge resection, other noncardiac mediastinal procedures) Closed tube thoracostomy	<i>Streptococcus pneumoniae</i> ; gram-negative bacilli	
Vascular	<i>Staphylococcus aureus</i> ; coagulase-negative staphylococci	250,463,476,477
Appendectomy	Gram-negative bacilli; anaerobes	263,452,478
Biliary tract	Gram-negative bacilli; anaerobes	260,262,479-484
Colorectal	Gram-negative bacilli; anaerobes	200,239,256,287 289,485-490
Gastroduodenal	Gram-negative bacilli; streptococci; oropharyngeal anaerobes (e.g., peptostreptococci)	256,257,491-493
Head and neck (major procedures with incision through oropharyngeal mucosa)	<i>Staphylococcus aureus</i> ; streptococci; oropharyngeal anaerobes (e.g., peptostreptococci)	494-497
Obstetric and gynecologic	Gram-negative bacilli; enterococci; group B streptococci; anaerobes	270-280,435
Urologic	Gram-negative bacilli	267
May not be beneficial if urine is sterile		

\*Refer to "Antimicrobial prophylaxis in surgery," The Medical Letter, 1997,<sup>266</sup> for current recommendations of antimicrobial agents and doses.

†Likely pathogens from both endogenous and exogenous sources.

‡Staphylococci will be associated with SSI following all types of operations.

ogy and prevention, strictly refers to a variable that has a significant, independent association with the development of SSI after a specific operation. Risk factors are identified by multivariate analyses in epidemiologic studies. Unfortunately, the term risk factor often is used in the surgical literature in a broad sense to include patient or operation features which, although associated with SSI development in univariate analysis, are not necessarily independent predictors.<sup>80</sup> The literature cited in the sections that follow includes risk factors identified by both univariate and multivariate analyses.

Table 5 lists patient and operation characteristics that may influence the risk of SSI development. These characteristics are useful in two ways: (1) they allow stratification of operations, making surveillance data

more comprehensible; and, (2) knowledge of risk factors before certain operations may allow for targeted prevention measures. For example, if it is known that a patient has a remote site infection, the surgical team may reduce SSI risk by scheduling an operation after the infection has resolved.

An SSI prevention measure can be defined as an action or set of actions intentionally taken to reduce the risk of an SSI. Many such techniques are directed at reducing opportunities for microbial contamination of the patient's tissues or sterile surgical instruments; others are adjunctive, such as using antimicrobial prophylaxis or avoiding unnecessary traumatic tissue dissection. Optimum application of SSI prevention measures requires that a variety of patient and operation characteristics be carefully considered.

## 1. Patient characteristics

In certain kinds of operations, patient characteristics possibly associated with an increased risk of an SSI include coincident remote site infections<sup>59-68</sup> or colonization,<sup>81-83</sup> diabetes,<sup>84-87</sup> cigarette smoking,<sup>85,88-92</sup> systemic steroid use,<sup>84,87,93</sup> obesity (>20% ideal body weight),<sup>85-87,94-97</sup> extremes of age,<sup>92,98-102</sup> poor nutritional status,<sup>85,94,98,103-105</sup> and perioperative transfusion of certain blood products.<sup>106-109</sup>

### a. Diabetes

The contribution of diabetes to SSI risk is controversial,<sup>84-86,98,110</sup> because the independent contribution of diabetes to SSI risk has not typically been assessed after controlling for potential confounding factors. Recent preliminary findings from a study of patients who underwent coronary artery bypass graft showed a significant relationship between increasing levels of HgA1c and SSI rates.<sup>111</sup> Also, increased glucose levels (>200 mg/dL) in the immediate postoperative period (≤48 hours) were associated with increased SSI risk.<sup>112,113</sup> More studies are needed to assess the efficacy of perioperative blood glucose control as a prevention measure.

### b. Nicotine use

Nicotine use delays primary wound healing and may increase the risk of SSI.<sup>85</sup> In a large prospective study, current cigarette smoking was an independent risk factor for sternal and/or mediastinal SSI following cardiac surgery.<sup>85</sup> Other studies have corroborated cigarette smoking as an important SSI risk factor.<sup>88-92</sup> The limitation of these studies, however, is that terms like *current cigarette smoking* and *active smokers* are not always defined. To appropriately determine the contribution of tobacco use to SSI risk, standardized definitions of smoking history must be adopted and used in studies designed to control for confounding variables.

### c. Steroid use

Patients who are receiving steroids or other immunosuppressive drugs preoperatively may be predisposed to developing SSI,<sup>84,87</sup> but the data supporting this relationship are contradictory. In a study of long-term steroid use in patients with Crohn's disease, SSI developed significantly more often in patients receiving preoperative steroids (12.5%) than in patients without steroid use (6.7%).<sup>93</sup> In contrast, other investigations have not found a relationship between steroid use and SSI risk.<sup>98,114,115</sup>

### d. Malnutrition

For some types of operations, severe protein-calorie malnutrition is crudely associated with postoperative nosocomial infections, impaired wound healing dynamics, or death.<sup>116-124</sup> The National Academy of Sciences/National Research Council (NAS/NRC),<sup>94</sup> Study on the Efficacy of Infection Control (SENIC),<sup>125</sup> and NNIS<sup>126</sup> schemes for SSI risk stratification do not

**Table 5.** Patient and Operation Characteristics That May Influence the Risk of Surgical Site Infection Development

Patient
Age
Nutritional status
Diabetes
Smoking
Obesity
Coexistent infections at a remote body site
Colonization with microorganisms
Altered immune response
Length of preoperative stay
Operation
Duration of surgical scrub
Skin antisepsis
Preoperative shaving
Preoperative skin prep
Duration of operation
Antimicrobial prophylaxis
Operating room ventilation
Inadequate sterilization of instruments
Foreign material in the surgical site
Surgical drains
Surgical technique
Poor hemostasis
Failure to obliterate dead space
Tissue trauma

Adapted from references 25, 37.

explicitly incorporate nutritional status as a predictor variable, although it may be represented indirectly in the latter two. In a widely quoted 1987 study of 404 high-risk general surgery operations, Christou and coworkers derived an SSI probability index in which final predictor variables were patient age, operation duration, serum albumin level, delayed hypersensitivity test score, and intrinsic wound contamination level.<sup>117</sup> Although this index predicted SSI risk satisfactorily for 404 subsequent patients and was generally received as a significant advance in SSI risk stratification, it is not widely used in SSI surveillance data analysis, surgical infection research, or analytic epidemiology.

Theoretical arguments can be made for a belief that severe preoperative malnutrition should increase the risk of both incisional and organ/space SSI. However, an epidemiologic association between incisional SSI and malnutrition is difficult to demonstrate consistently for all surgical subspecialties.<sup>118-120,124,127-131</sup> Multivariate logistic regression modeling has shown that preoperative protein-calorie malnutrition is not an independent predictor of mediastinitis after cardiac bypass operations.<sup>85,132</sup>

In the modern era, total parenteral nutrition (TPN) and total enteral alimentation (TEA) have enthusiastic acceptance by surgeons and critical care specialists.<sup>118,133-137</sup> However, the benefits of preoperative nutritional repletion of malnourished patients in reducing

SSI risk are unproven. In two randomized clinical trials, preoperative "nutritional therapy" did not reduce incisional and organ/space SSI risk.<sup>138-141</sup> In a recent study of high-risk pancreatectomy patients with cancer, the provision of TPN preoperatively had no beneficial effect on SSI risk.<sup>142</sup> A randomized prospective trial involving 395 general and thoracic surgery patients compared outcomes for malnourished patients preoperatively receiving either a 7- to 15-day TPN regimen or a regular preoperative hospital diet. All patients were followed for 90 days postoperatively. There was no detectable benefit of TPN administration on the incidence of incisional or organ/space SSI.<sup>143</sup> Administering TPN or TEA may be indicated in a number of circumstances, but such repletion cannot be viewed narrowly as a prevention measure for organ/space or incisional SSI risk. When a major elective operation is necessary in a severely malnourished patient, experienced surgeons often use both pre- and postoperative nutritional support in consideration of the major morbidity associated with numerous potential complications, only one of which is organ/space SSI.<sup>118,124,130,133,137,138,144-149</sup> In addition, postoperative nutritional support is important for certain major oncologic operations,<sup>135,136</sup> after many operations on major trauma victims,<sup>134</sup> or in patients suffering a variety of catastrophic surgical complications that preclude eating or that trigger a hypermetabolic state. Randomized clinical trials will be necessary to determine if nutritional support alters SSI risk in specific patient-operation combinations.

#### e. Prolonged preoperative hospital stay

Prolonged preoperative hospital stay is frequently suggested as a patient characteristic associated with increased SSI risk. However, length of preoperative stay is likely a surrogate for severity of illness and co-morbid conditions requiring inpatient work-up and/or therapy before the operation.<sup>16,26,65,85,94,100,150,151</sup>

#### f. Preoperative nares colonization with *Staphylococcus aureus*

*S. aureus* is a frequent SSI isolate. This pathogen is carried in the nares of 20% to 30% of healthy humans.<sup>81</sup> It has been known for years that the development of SSI involving *S. aureus* is definitely associated with preoperative nares carriage of the organism in surgical patients.<sup>81</sup> A recent multivariate analysis demonstrated that such carriage was the most powerful independent risk factor for SSI following cardiothoracic operations.<sup>82</sup>

Mupirocin ointment is effective as a topical agent for eradicating *S. aureus* from the nares of colonized patients or healthcare workers. A recent report by Kluytmans and coworkers suggested that SSI risk was reduced in patients who had cardiothoracic operations when mupirocin was applied preoperatively to their nares, regardless of carrier status.<sup>152</sup> In this study, SSI

rates for 752 mupirocin-treated patients were compared with those previously observed for an untreated group of 928 historical control patients, and the significant SSI rate reduction was attributed to the mupirocin treatment. Concerns have been raised regarding the comparability of the two patient groups.<sup>153</sup> Additionally, there is concern that mupirocin resistance may emerge, although this seems unlikely when treatment courses are brief.<sup>81</sup> A prospective, randomized clinical trial will be necessary to establish definitively that eradication of nasal carriage of *S. aureus* is an effective SSI prevention method in cardiac surgery. Such a trial has recently been completed on 3,909 patients in Iowa.<sup>83</sup> Five types of operations in two facilities were observed. Preliminary analysis showed a significant association between nasal carriage of *S. aureus* and subsequent SSI development. The effect of mupirocin on reducing SSI risk is yet to be determined.

#### g. Perioperative transfusion

It has been reported that perioperative transfusion of leukocyte-containing allogeneic blood components is an apparent risk factor for the development of postoperative bacterial infections, including SSI.<sup>106</sup> In three of five randomized trials conducted in patients undergoing elective colon resection for cancer, the risk of SSI was at least doubled in patients receiving blood transfusions.<sup>107-109</sup> However, on the basis of detailed epidemiologic reconsiderations, as many as 12 confounding variables may have influenced the reported association, and any effect of transfusion on SSI risk may be either small or nonexistent.<sup>106</sup> Because of methodologic problems, including the timing of transfusion, and use of nonstandardized SSI definitions, interpretation of the available data is limited. A meta-analysis of published trials will probably be required for resolution of the controversy.<sup>154</sup> There is currently no scientific basis for withholding necessary blood products from surgical patients as a means of either incisional or organ/space SSI risk reduction.

## 2. Operative characteristics: Preoperative issues

#### a. Preoperative antiseptic showering

A preoperative antiseptic shower or bath decreases skin microbial colony counts. In a study of >700 patients who received two preoperative antiseptic showers, chlorhexidine reduced bacterial colony counts ninefold ( $2.8 \times 10^2$  to 0.3), while povidone-iodine or triclocarban-medicated soap reduced colony counts by 1.3- and 1.9-fold, respectively.<sup>155</sup> Other studies corroborate these findings.<sup>156,157</sup> Chlorhexidine gluconate-containing products require several applications to attain maximum antimicrobial benefit, so repeated antiseptic showers are usually indicated.<sup>158</sup> Even though preoperative showers reduce the skin's microbial colony counts, they have not definitively been shown to reduce SSI rates.<sup>159-165</sup>

**Table 6.** Mechanism and Spectrum of Activity of Antiseptic Agents Commonly Used for Preoperative Skin Preparation and Surgical Scrubs

Agent	Mechanism of Action	Gram-Positive Bacteria	Gram-Negative Bacteria	Mtb	Fungi	Virus	Rapidity of Action	Residual Activity	Toxicity	Uses
Alcohol	Denature proteins	E	E	G	G	G	Most rapid	None	Drying, volatile	SP, SS
Chlorhexidine	Disrupt cell membrane	E	G	P	F	G	Intermediate	E	Ototoxicity, keratitis	SP, SS
Iodine/Iodophors	Oxidation/substitution by free iodine	E	G	G	G	G	Intermediate	Minimal	Absorption from skin with possible toxicity, skin irritation	SP, SS
PCMX	Disrupt cell wall	G	F*	F	F	F	Intermediate	Good	More data needed	SS
Triclosan	Disrupt cell wall	G	G	G	P	U	Intermediate	E	More data needed	SS

Abbreviations: E, excellent; F, fair; G, good; Mtb, *Mycobacterium tuberculosis*; P, poor; PCMX, para-chloro-meta-xlenol; SP, skin preparation; SS, surgical scrubs; U, unknown.

Data from Larson E.<sup>176</sup>

\*Fair, except for *Pseudomonas* spp.; activity improved by addition of chelating agent such as EDTA.

### b. Preoperative hair removal

Preoperative shaving of the surgical site the night before an operation is associated with a significantly higher SSI risk than either the use of depilatory agents or no hair removal.<sup>16,100,166-169</sup> In one study, SSI rates were 5.6% in patients who had hair removed by razor shave compared to a 0.6% rate among those who had hair removed by depilatory or who had no hair removed.<sup>166</sup> The increased SSI risk associated with shaving has been attributed to microscopic cuts in the skin that later serve as foci for bacterial multiplication. Shaving immediately before the operation compared to shaving within 24 hours preoperatively was associated with decreased SSI rates (3.1% vs 7.1%); if shaving was performed >24 hours prior to operation, the SSI rate exceeded 20%.<sup>166</sup> Clipping hair immediately before an operation also has been associated with a lower risk of SSI than shaving or clipping the night before an operation (SSI rates immediately before = 1.8% vs night before = 4.0%).<sup>170-173</sup> Although the use of depilatories has been associated with a lower SSI risk than shaving or clipping,<sup>166,167</sup> depilatories sometimes produce hypersensitivity reactions.<sup>166</sup> Other studies showed that preoperative hair removal by any means was associated with increased SSI rates and suggested that no hair be removed.<sup>100,174,175</sup>

### c. Patient skin preparation in the operating room

Several antiseptic agents are available for preoperative preparation of skin at the incision site (Table 6). The iodophors (e.g., povidone-iodine), alcohol-containing products, and chlorhexidine gluconate are the most commonly used agents. No studies have adequately assessed the comparative effects of these preoperative

skin antiseptics on SSI risk in well-controlled, operation-specific studies.

Alcohol is defined by the FDA as having one of the following active ingredients: ethyl alcohol, 60% to 95% by volume in an aqueous solution, or isopropyl alcohol, 50% to 91.3% by volume in an aqueous solution.<sup>12</sup> Alcohol is readily available, inexpensive, and remains the most effective and rapid-acting skin antiseptic.<sup>176</sup> Aqueous 70% to 92% alcohol solutions have germicidal activity against bacteria, fungi, and viruses, but spores can be resistant.<sup>176,177</sup> One potential disadvantage of the use of alcohol in the operating room is its flammability.<sup>176-178</sup>

Both chlorhexidine gluconate and iodophors have broad spectra of antimicrobial activity.<sup>177,179-181</sup> In some comparisons of the two antiseptics when used as preoperative hand scrubs, chlorhexidine gluconate achieved greater reductions in skin microflora than did povidone-iodine and also had greater residual activity after a single application.<sup>182-184</sup> Further, chlorhexidine gluconate is not inactivated by blood or serum proteins.<sup>176,179,185,186</sup> Iodophors may be inactivated by blood or serum proteins, but exert a bacteriostatic effect as long as they are present on the skin.<sup>178,179</sup>

Before the skin preparation of a patient is initiated, the skin should be free of gross contamination (i.e., dirt, soil, or any other debris).<sup>187</sup> The patient's skin is prepared by applying an antiseptic in concentric circles, beginning in the area of the proposed incision. The prepared area should be large enough to extend the incision or create new incisions or drain sites, if necessary.<sup>1,177,187</sup> The application of the skin preparation may need to be modified, depending on the condition of the skin (e.g., burns) or location of the incision site (e.g., face).

There are reports of modifications to the procedure for preoperative skin preparation which include: (1) removing or wiping off the skin preparation antiseptic agent after application, (2) using an antiseptic-impregnated adhesive drape, (3) merely painting the skin with an antiseptic in lieu of the skin preparation procedure described above, or (4) using a "clean" versus a "sterile" surgical skin preparation kit.<sup>188-191</sup> However, none of these modifications has been shown to represent an advantage.

#### d. Preoperative hand/forearm antisepsis

Members of the surgical team who have direct contact with the sterile operating field or sterile instruments or supplies used in the field wash their hands and forearms by performing a traditional procedure known as scrubbing (or the surgical scrub) immediately before donning sterile gowns and gloves. Ideally, the optimum antiseptic used for the scrub should have a broad spectrum of activity, be fast-acting, and have a persistent effect.<sup>1,192,193</sup> Antiseptic agents commercially available in the United States for this purpose contain alcohol, chlorhexidine, iodine/iodophors, para-chloro-meta-xyleneol, or triclosan (Table 6).<sup>176,177,179,194,195</sup> Alcohol is considered the gold standard for surgical hand preparation in several European countries.<sup>196-199</sup> Alcohol-containing products are used less frequently in the United States than in Europe, possibly because of concerns about flammability and skin irritation. Povidone-iodine and chlorhexidine gluconate are the current agents of choice for most U.S. surgical team members.<sup>177</sup> However, when 7.5% povidone-iodine or 4% chlorhexidine gluconate was compared to alcoholic chlorhexidine (60% isopropanol and 0.5% chlorhexidine gluconate in 70% isopropanol), alcoholic chlorhexidine was found to have greater residual antimicrobial activity.<sup>200,201</sup> No agent is ideal for every situation, and a major factor, aside from the efficacy of any product, is its acceptability by operating room personnel after repeated use. Unfortunately, most studies evaluating surgical scrub antiseptics have focused on measuring hand bacterial colony counts. No clinical trials have evaluated the impact of scrub agent choice on SSI risk.<sup>195,202-206</sup>

Factors other than the choice of antiseptic agent influence the effectiveness of the surgical scrub. Scrubbing technique, the duration of the scrub, the condition of the hands, or the techniques used for drying and gloving are examples of such factors. Recent studies suggest that scrubbing for at least 2 minutes is as effective as the traditional 10-minute scrub in reducing hand bacterial colony counts,<sup>207-211</sup> but the optimum duration of scrubbing is not known. The first scrub of the day should include a thorough cleaning underneath fingernails (usually with a brush).<sup>180,194,212</sup> It is not clear that such cleaning is a necessary part of subsequent

scrubs during the day. After performing the surgical scrub, hands should be kept up and away from the body (elbows in flexed position) so that water runs from the tips of the fingers toward the elbows. Sterile towels should be used for drying the hands and forearms before the donning of a sterile gown and gloves.<sup>212</sup>

A surgical team member who wears artificial nails may have increased bacterial and fungal colonization of the hands despite performing an adequate hand scrub.<sup>212,213</sup> Hand carriage of gram-negative organisms has been shown to be greater among wearers of artificial nails than among non-wearers.<sup>213</sup> An outbreak of *Serratia marcescens* SSIs in cardiovascular surgery patients was found to be associated with a surgical nurse who wore artificial nails.<sup>214</sup> While the relationship between nail length and SSI risk is unknown, long nails—artificial or natural—may be associated with tears in surgical gloves.<sup>177,180,212</sup> The relationship between the wearing of nail polish or jewelry by surgical team members and SSI risk has not been adequately studied.<sup>194,212,215-217</sup>

#### e. Management of infected or colonized surgical personnel

Surgical personnel who have active infections or are colonized with certain microorganisms have been linked to outbreaks or clusters of SSIs.<sup>33,34,76,218-237</sup> Thus, it is important that healthcare organizations implement policies to prevent transmission of microorganisms from personnel to patients. These policies should address management of job-related illnesses, provision of postexposure prophylaxis after job-related exposures and, when necessary, exclusion of ill personnel from work or patient contact. While work exclusion policies should be enforceable and include a statement of authority to exclude ill personnel, they should also be designed to encourage personnel to report their illnesses and exposures and not penalize personnel with loss of wages, benefits, or job status.<sup>238</sup>

#### f. Antimicrobial prophylaxis

Surgical antimicrobial prophylaxis (AMP) refers to a very brief course of an antimicrobial agent initiated just before an operation begins.<sup>239-265</sup> AMP is not an attempt to sterilize tissues, but a critically timed adjunct used to reduce the microbial burden of intraoperative contamination to a level that cannot overwhelm host defenses. AMP does not pertain to prevention of SSI caused by postoperative contamination.<sup>265</sup> Intravenous infusion is the mode of AMP delivery used most often in modern surgical practice.<sup>20,26,242,266-281</sup> Essentially all confirmed AMP indications pertain to elective operations in which skin incisions are closed in the operating room.

Four principles must be followed to maximize the benefits of AMP:

- Use an AMP agent for all operations or classes of operations in which its use has been shown to reduce SSI rates based on evidence from clinical trials or for those operations after which incisional or organ/space SSI would represent a catastrophe.<sup>266,268,269,282-284</sup>
- Use an AMP agent that is safe, inexpensive, and bactericidal with an in vitro spectrum that covers the most probable intraoperative contaminants for the operation.
- Time the infusion of the initial dose of antimicrobial agent so that a bactericidal concentration of the drug is established in serum and tissues by the time the skin is incised.<sup>285</sup>
- Maintain therapeutic levels of the antimicrobial agent in both serum and tissues throughout the operation and until, at most, a few hours after the incision is closed in the operating room.<sup>179,266-268,282,284,286</sup> Because clotted blood is present in all surgical wounds, therapeutic serum levels of AMP agents are logically important in addition to therapeutic tissue levels. Fibrin-enmeshed bacteria may be resistant to phagocytosis or to contact with antimicrobial agents that diffuse from the wound space.

Table 4 summarizes typical SSI pathogens according to operation type and cites studies that establish AMP efficacy for these operations. A simple way to organize AMP indications is based on using the surgical wound classification scheme shown in Table 7, which employs descriptive case features to *postoperatively* grade the degree of intraoperative microbial contamination. A surgeon makes the decision to use AMP by anticipating *preoperatively* the surgical wound class for a given operation.

AMP is indicated for all operations that entail entry into a hollow viscus under controlled conditions. The most frequent SSI pathogens for such clean-contaminated operations are listed in Table 4. Certain clean-contaminated operations, such as elective colon resection, low anterior resection of the rectum, and abdominoperineal resection of the rectum, also require an additional preoperative protective maneuver called "preparation of the colon," to empty the bowel of its contents and to reduce the levels of live microorganisms.<sup>200,239,256,268,284,287</sup> This maneuver includes the administration of enemas and cathartic agents followed by the oral administration of nonabsorbable antimicrobial agents in divided doses the day before the operation.<sup>200,288,289</sup>

AMP is sometimes indicated for operations that entail incisions through normal tissue and in which no viscus is entered and no inflammation or infection is encountered. Two well-recognized AMP indications for such clean operations are: (1) when any intravascular

**Table 7.** Surgical Wound Classification

*Class I/Clean:* An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tract is not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow nonpenetrating (blunt) trauma should be included in this category if they meet the criteria.

*Class II/Clean-Contaminated:* An operative wound in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered.

*Class III/Contaminated:* Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered are included in this category.

*Class IV/Dirty-Infected:* Old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.

Garner JS<sup>1</sup> and Simmons BP.<sup>2</sup>

prosthetic material or a prosthetic joint will be inserted, and (2) for any operation in which an incisional or organ/space SSI would pose catastrophic risk. Examples are all cardiac operations, including cardiac pacemaker placement,<sup>290</sup> vascular operations involving prosthetic arterial graft placement at any site or the revascularization of the lower extremity, and most neurosurgical operations (Table 4). Some have advocated use of AMP during all operations on the breast.<sup>80,242,264</sup>

By definition, AMP is not indicated for an operation classified in Table 7 as contaminated or dirty. In such operations, patients are frequently receiving therapeutic antimicrobial agents perioperatively for established infections.

Cephalosporins are the most thoroughly studied AMP agents.<sup>284</sup> These drugs are effective against many gram-positive and gram-negative microorganisms. They also share the features of demonstrated safety, acceptable pharmacokinetics, and a reasonable cost per dose.<sup>242</sup> In particular, cefazolin is widely used and generally viewed as the AMP agent of first choice for clean operations.<sup>266</sup> If a patient is unable to receive a cephalosporin because of penicillin allergy, an alternative for gram-positive bacterial coverage is either clindamycin or vancomycin.

Cefazolin provides adequate coverage for many clean-contaminated operations,<sup>268,291</sup> but AMP for operations on the distal intestinal tract mandates use of an agent such as cefoxitin (or some other second-genera-

tion cephalosporin) that provides anaerobic coverage. If a patient cannot safely receive a cephalosporin because of allergy, a reasonable alternative for gram-negative coverage is aztreonam. However, an agent such as clindamycin or metronidazole should also be included to ensure anaerobic coverage.

The aminoglycosides are seldom recommended as first choices for AMP, either as single drugs or as components of combination regimens.<sup>242,264</sup> References cited in Table 4 provide many details regarding AMP choices and dosages, antimicrobial spectra and properties, and other practical clinical information.

The routine use of vancomycin in AMP is not recommended for any kind of operation.<sup>242,266,283,292</sup> However, vancomycin may be the AMP agent of choice in certain clinical circumstances, such as when a cluster of MRSA mediastinitis or incisional SSI due to methicillin-resistant coagulase-negative staphylococci has been detected. A threshold has not been scientifically defined that can support the decision to use vancomycin in AMP. The decision should involve consideration of local frequencies of MRSA isolates, SSI rates for particular operations, review of infection prevention practices for compliance, and consultation between surgeons and infectious disease experts. An effective SSI surveillance program must be operational, with careful and timely culturing of SSI isolates to determine species and AMP agent susceptibilities.<sup>80</sup>

Agents most commonly used for AMP (i.e., cephalosporins) exhibit time-dependent bactericidal action. The therapeutic effects of such agents are probably maximized when their levels continuously exceed a threshold value best approximated by the minimal bactericidal concentration value observed for the target pathogens *in vitro*. When the duration of an operation is expected to exceed the time in which therapeutic levels of the AMP agent can be maintained, additional AMP agent should be infused. That time point for cefazolin is estimated as 3 to 4 hours. In general, the timing of a second (or third, etc.) dose of any AMP drug is estimated from three parameters: tissue levels achieved in normal patients by a standard therapeutic dose, the approximate serum half-life of the drug, and awareness of approximate MIC<sub>90</sub> values for anticipated SSI pathogens. References in Table 6 should be consulted for these details and important properties of antimicrobial agents used for AMP in various specialties.

Basic "rules of thumb" guide decisions about AMP dose sizes and timing. For example, it is believed that a full therapeutic dose of cefazolin (1-2 g) should be given to adult patients no more than 30 minutes before the skin is incised.<sup>242,285</sup> There are a few exceptions to this basic guide. With respect to dosing, it has been demonstrated that larger doses of AMP agents are necessary to

achieve optimum effect in morbidly obese patients.<sup>293</sup> With respect to timing, an exception occurs for patients undergoing cesarean section in whom AMP is indicated: the initial dose is administered immediately after the umbilical cord is clamped.<sup>266,272,273</sup> If vancomycin is used, an infusion period of approximately 1 hour is required for a typical dose. Clearly, the concept of "on-call" infusion of AMP is flawed simply because delays in transport or schedule changes can mean that suboptimal tissue and serum levels may be present when the operation starts.<sup>242,294</sup> Simple protocols of AMP timing and oversight responsibility should be locally designed to be practical and effective.

### 3. Operative characteristics: Intraoperative issues

#### a. Operating room environment

##### (1) Ventilation

Operating room air may contain microbial-laden dust, lint, skin squames, or respiratory droplets. The microbial level in operating room air is directly proportional to the number of people moving about in the room.<sup>295</sup> Therefore, efforts should be made to minimize personnel traffic during operations. Outbreaks of SSIs caused by group A beta-hemolytic streptococci have been traced to airborne transmission of the organism from colonized operating room personnel to patients.<sup>233,237,296,297</sup> In these outbreaks, the strain causing the outbreak was recovered from the air in the operating room.<sup>237,296</sup> It has been demonstrated that exercising and changing of clothing can lead to airborne dissemination of group A streptococci from vaginal or rectal carriage.<sup>233,234,237,297</sup>

Operating rooms should be maintained at positive pressure with respect to corridors and adjacent areas.<sup>298</sup> Positive pressure prevents airflow from less clean areas into more clean areas. All ventilation or air conditioning systems in hospitals, including those in operating rooms, should have two filter beds in series, with the efficiency of the first filter bed being  $\geq 30\%$  and that of the second filter bed being  $\geq 90\%$ .<sup>299</sup> Conventional operating room ventilation systems produce a minimum of about 15 air changes of filtered air per hour, three (20%) of which must be fresh air.<sup>299,300</sup> Air should be introduced at the ceiling and exhausted near the floor.<sup>300,301</sup> Detailed ventilation parameters for operating rooms have been published by the American Institute of Architects in collaboration with the U.S. Department of Health and Human Services (Table 8).<sup>299</sup>

Laminar airflow and use of UV radiation have been suggested as additional measures to reduce SSI risk for certain operations. Laminar airflow is designed to move particle-free air (called "ultraclean air") over the aseptic operating field at a uniform velocity (0.3 to 0.5  $\mu\text{m}/\text{sec}$ ),

sweeping away particles in its path. Laminar airflow can be directed vertically or horizontally, and recirculated air is usually passed through a high efficiency particulate air (HEPA) filter.<sup>302,303</sup> HEPA filters remove particles  $\geq 0.3\mu\text{m}$  in diameter with an efficiency of 99.97%.<sup>64,300,302,304</sup> Most of the studies examining the efficacy of ultraclean air involve only orthopedic operations.<sup>298,305-311</sup> Charnley and Eftaknan studied vertical laminar airflow systems and exhaust-ventilated clothing and found that their use decreased the SSI rate from 9% to 1%.<sup>305</sup> However, other variables (i.e., surgeon experience and surgical technique) changed at the same time as the type of ventilation, which may have confounded the associations. In a multicenter study examining 8,000 total hip and knee replacements, Lidwell et al. compared the effects of ultraclean air alone, antimicrobial prophylaxis alone, and ultraclean air in combination with antimicrobial prophylaxis on the rate of deep SSIs.<sup>307</sup> The SSI rate following operations in which ultraclean air alone was used decreased from 3.4% to 1.6%, whereas the rate for those who received only antimicrobial prophylaxis decreased from 3.4% to 0.8%. When both interventions were used in combination, the SSI rate decreased from 3.4% to 0.7%. These findings suggest that both ultraclean air and antimicrobial prophylaxis can reduce the incidence of SSI following orthopedic implant operations, but antimicrobial prophylaxis is more beneficial than ultraclean air. Intraoperative UV radiation has not been shown to decrease overall SSI risk.<sup>94,312</sup>

## (2) Environmental surfaces

Environmental surfaces in U.S. operating rooms (e.g., tables, floors, walls, ceilings, lights) are rarely implicated as the sources of pathogens important in the development of SSIs. Nevertheless, it is important to perform routine cleaning of these surfaces to reestablish a clean environment after each operation.<sup>180,212,300,302</sup> There are no data to support routine disinfecting of environmental surfaces or equipment between operations in the absence of contamination or visible soiling. When visible soiling of surfaces or equipment occurs during an operation, an Environmental Protection Agency (EPA)-approved hospital disinfectant should be used to decontaminate the affected areas before the next operation.<sup>180,212,300-302,313-315</sup> This is in keeping with the Occupational Safety and Health Administration (OSHA) requirement that all equipment and environmental surfaces be cleaned and decontaminated after contact with blood or other potentially infectious materials.<sup>315</sup> Wet-vacuuming of the floor with an EPA-approved hospital disinfectant is performed routinely after the last operation of the day or night. Care should be taken to ensure that medical equipment left in the operating room be covered so that solutions used during cleaning and dis-

**Table 8** Parameters for Operating Room Ventilation, American Institute of Architects, 1996

Temperature	68-73°F, depending on normal ambient temperatures
Relative humidity	30%-60%
Air movement	From "clean to less clean" areas
Air changes	Minimum 15 total air changes per hour Minimum 3 air changes of outdoor air per hour

American Institute of Architects.<sup>299</sup>

infecting do not contact sterile devices or equipment.<sup>316</sup> There are no data to support special cleaning procedures or closing of an operating room after a contaminated or dirty operation has been performed.<sup>300,301</sup>

Tacky mats placed outside the entrance to an operating room/suite have not been shown to reduce the number of organisms on shoes or stretcher wheels, nor do they reduce the risk of SSI.<sup>1,179,295,301</sup>

## (3) Microbiologic sampling

Because there are no standardized parameters by which to compare microbial levels obtained from cultures of ambient air or environmental surfaces in the operating room, routine microbiologic sampling cannot be justified. Such environmental sampling should only be performed as part of an epidemiologic investigation.

## (4) Conventional sterilization of surgical instruments

Inadequate sterilization of surgical instruments has resulted in SSI outbreaks.<sup>302,317,318</sup> Surgical instruments can be sterilized by steam under pressure, dry heat, ethylene oxide, or other approved methods. The importance of routinely monitoring the quality of sterilization procedures has been established.<sup>1,180,212,299</sup> Microbial monitoring of steam autoclave performance is necessary and can be accomplished by use of a biological indicator.<sup>212,314,319</sup> Detailed recommendations for sterilization of surgical instruments have been published.<sup>212,314,320,321</sup>

## (5) Flash sterilization of surgical instruments

The Association for the Advancement of Medical Instrumentation defines flash sterilization as "the process designated for the steam sterilization of patient care items for immediate use."<sup>321</sup> During any operation, the need for emergency sterilization of equipment may arise (e.g., to reprocess an inadvertently dropped instrument). However, flash sterilization is not intended to be used for either reasons of convenience or as an alternative to purchasing additional instrument sets or to save time. Also, flash sterilization is not recommended for implantable devices<sup>(\*)</sup> because of the potential for serious infections.<sup>314,320,321</sup>

\*According to the FDA, an implantable device is a "device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more."<sup>321</sup>

Flash sterilization is not recommended as a routine sterilization method because of the lack of timely biologic indicators to monitor performance, absence of protective packaging following sterilization, possibility for contamination of processed items during transportation to operating rooms, and use of minimal sterilization cycle parameters (i.e., time, temperature, pressure).<sup>319</sup> To address some of these concerns, many hospitals have placed equipment for flash sterilization in close proximity to operating rooms and new biologic indicators that provide results in 1 to 3 hours are now available for flash-sterilized items.<sup>322-325</sup> Nevertheless, flash sterilization should be restricted to its intended purpose until studies are performed that can demonstrate comparability with conventional sterilization methods regarding risk of SSI. Sterilization cycle parameters for flash sterilization are shown in Table 9.

### **b. Surgical attire and drapes**

In this section the term *surgical attire* refers to scrub suits, caps/hoods, shoe covers, masks, gloves, and gowns. Although experimental data show that live microorganisms are shed from hair, exposed skin, and mucous membranes of operating room personnel,<sup>75,181,326-330</sup> few controlled clinical studies have evaluated the relationship between the use of surgical attire and SSI risk. Nevertheless, the use of barriers seems prudent to minimize a patient's exposure to the skin, mucous membranes, or hair of surgical team members, as well as to protect surgical team members from exposure to blood and bloodborne pathogens (e.g., human immunodeficiency virus and hepatitis viruses).

#### *(1) Scrub suits*

Surgical team members often wear a uniform called a "scrub suit" that consists of pants and a shirt. Policies for laundering, wearing, covering, and changing scrub suits vary greatly. Some policies restrict the laundering of scrub suits to the facility, while other facilities have policies that allow laundering by employees. There are no well-controlled studies evaluating scrub suit laundering as an SSI risk factor.<sup>331</sup> Some facilities have policies that restrict the wearing of scrub suits to the operating suite, while other facilities allow the wearing of cover gowns over scrub suits when personnel leave the suite. The Association of Operating Room Nurses recommends that scrub suits be changed after they become visibly soiled and that they be laundered only in an approved and monitored laundry facility.<sup>212</sup> Additionally, OSHA regulations require that "if a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible."<sup>315</sup>

#### *(2) Masks*

The wearing of surgical masks during operations to prevent potential microbial contamination of inci-

sions is a longstanding surgical tradition. However, some studies have raised questions about the efficacy and cost-benefit of surgical masks in reducing SSI risk.<sup>328,332-338</sup> Nevertheless, wearing a mask can be beneficial since it protects the wearer's nose and mouth from inadvertent exposures (i.e., splashes) to blood and other body fluids. OSHA regulations require that masks in combination with protective eyewear, such as goggles or glasses with solid shields, or chin-length face shields be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious material may be generated and eye, nose, or mouth contamination can be reasonably anticipated.<sup>315</sup> In addition, a respirator certified by the National Institute for Occupational Safety and Health with protection factor N95 or higher is required when the patient has or is suspected of having infectious tuberculosis.<sup>339</sup>

#### *(3) Surgical caps/hoods and shoe covers*

Surgical caps/hoods are inexpensive and reduce contamination of the surgical field by organisms shed from the hair and scalp. SSI outbreaks have occasionally been traced to organisms isolated from the hair or scalp (*S. aureus* and group A *Streptococcus*),<sup>75,76</sup> even when caps were worn by personnel during the operation and in the operating suites.

The use of shoe covers has never been shown to decrease SSI risk or to decrease bacteria counts on the operating room floor.<sup>340,341</sup> Shoe covers may, however, protect surgical team members from exposure to blood and other body fluids during an operation. OSHA regulations require that surgical caps or hoods and shoe covers or boots be worn in situations when gross contamination can reasonably be anticipated (e.g., orthopedic operations, penetrating trauma cases).<sup>315</sup>

#### *(4) Sterile gloves*

Sterile gloves are put on after donning sterile gowns. A strong theoretical rationale supports the wearing of sterile gloves by all scrubbed members of the surgical team. Sterile gloves are worn to minimize transmission of microorganisms from the hands of team members to patients and to prevent contamination of team members' hands with patients' blood and body fluids. If the integrity of a glove is compromised (e.g., punctured), it should be changed as promptly as safety permits.<sup>315,342,343</sup> Wearing two pairs of gloves (double-gloving) has been shown to reduce hand contact with patients' blood and body fluids when compared to wearing only a single pair.<sup>344,345</sup>

#### *(5) Gowns and drapes*

Sterile surgical gowns and drapes are used to create a barrier between the surgical field and potential sources of bacteria. Gowns are worn by all scrubbed surgical team members and drapes are placed over the

patient. There are limited data that can be used to understand the relationship of gown or drape characteristics with SSI risk. The wide variation in the products and study designs make interpretation of the literature difficult.<sup>329,346-350</sup>

Gowns and drapes are classified as disposable (single use) or reusable (multiple use). Regardless of the material used to manufacture gowns and drapes, these items should be impermeable to liquids and viruses.<sup>351,352</sup> In general, only gowns reinforced with films, coatings, or membranes appear to meet standards developed by the American Society for Testing and Materials.<sup>351-353</sup> However, such "liquid-proof" gowns may be uncomfortable because they also inhibit heat loss and the evaporation of sweat from the wearer's body. These factors should be considered when selecting gowns.<sup>353,354</sup> A discussion of the role of gowns and drapes in preventing the transmission of bloodborne pathogens is beyond the scope of this document.<sup>355</sup>

### c. Asepsis and surgical technique

#### (1) Asepsis

Rigorous adherence to the principles of asepsis by all scrubbed personnel is the foundation of surgical site infection prevention. Others who work in close proximity to the sterile surgical field, such as anesthesia personnel who are separated from the field only by a drape barrier, also must abide by these principles. SSIs have occurred in which anesthesia personnel were implicated as the source of the pathogen.<sup>34,231,234,356-358</sup> Anesthesiologists and nurse anesthetists perform a variety of invasive procedures such as placement of intravascular devices and endotracheal tubes, and administration of intravenous drugs and solutions. Lack of adherence to the principles of asepsis during such procedures,<sup>359</sup> including use of common syringes<sup>360,361</sup> and contaminated infusion pumps,<sup>359,362-364</sup> and the assembly of equipment and solutions in advance of procedures,<sup>316,360</sup> have been associated with outbreaks of postoperative infections, including SSI. Recommendations for infection control practices in anesthesiology have been published.<sup>212,365-367</sup>

#### (2) Surgical technique

Excellent surgical technique is widely believed to reduce the risk of SSI.<sup>26,49,179,180,368,369</sup> Such techniques include maintaining effective hemostasis while preserving adequate blood supply, preventing hypothermia, gently handling tissues, avoiding inadvertent entries into a hollow viscus, removing devitalized (e.g., necrotic or charred) tissues, using drains and suture material appropriately, eradicating dead space, and appropriately managing the postoperative incision.

**Table 9.** Parameters for Flash Sterilization Cycles, Association for the Advancement of Medical Instrumentation

	Minimum Exposure Time and Temperature
<b>Gravity-displacement</b>	
Nonporous items	3 min at 132°C (270°F)
Nonporous and porous items	10 min at 132°C (270°F)
<b>Prevacuum</b>	
Nonporous items	3 min at 132°C (270°F)
Nonporous and porous items	4 min at 132°C (270°F)

Association for the Advancement of Medical Instrumentation.<sup>321</sup>

Any foreign body, including suture material, a prosthesis, or drain, may promote inflammation at the surgical site<sup>94</sup> and may increase the probability of SSI after otherwise benign levels of tissue contamination. Extensive research compares different types of suture material and their presumed relationships to SSI risk.<sup>370-379</sup> In general, monofilament sutures appear to have the lowest infection-promoting effects.<sup>3,94,179,180</sup>

A discussion of appropriate surgical drain use and details of drain placement exceed the scope of this document, but general points should be briefly noted. Drains placed through an operative incision increase incisional SSI risk.<sup>380</sup> Many authorities suggest placing drains through a separate incision distant from the operative incision.<sup>283,381</sup> It appears that SSI risk also decreases when closed suction drains are used rather than open drains.<sup>174</sup> Closed suction drains can effectively evacuate postoperative hematomas or seromas, but timing of drain removal is important. Bacterial colonization of initially sterile drain tracts increases with the duration of time the drain is left in place.<sup>382</sup>

Hypothermia in surgical patients, defined as a core body temperature below 36°C, may result from general anesthesia, exposure to cold, or intentional cooling such as is done to protect the myocardium and central nervous system during cardiac operations.<sup>302,383,384</sup> In one study of patients undergoing colorectal operations, hypothermia was associated with an increased SSI risk.<sup>385</sup> Mild hypothermia appears to increase incisional SSI risk by causing vasoconstriction, decreased delivery of oxygen to the wound space, and subsequent impairment of function of phagocytic leukocytes (i.e., neutrophils).<sup>386-390</sup> In animal models, supplemental oxygen administration has been shown to reverse the dysfunction of phagocytes in fresh incisions.<sup>391</sup> In recent human experiments, controlled local heating of incisions with an electrically powered bandage has been shown to improve tissue oxygenation.<sup>392</sup> Randomized clinical trials are needed to establish that measures which improve wound space oxygenation can reduce SSI risk.

#### 4. Operative characteristics: Postoperative issues

##### a. Incision care

The type of postoperative incision care is determined by whether the incision is closed primarily (i.e., the skin edges are re-approximated at the end of the operation), left open to be closed later, or left open to heal by second intention. When a surgical incision is closed primarily, as most are, the incision is usually covered with a sterile dressing for 24 to 48 hours.<sup>393,394</sup> Beyond 48 hours, it is unclear whether an incision must be covered by a dressing or whether showering or bathing is detrimental to healing. When a surgical incision is left open at the skin level for a few days before it is closed (delayed primary closure), a surgeon has determined that it is likely to be contaminated or that the patient's condition prevents primary closure (e.g., edema at the site). When such is the case, the incision is packed with a sterile dressing. When a surgical incision is left open to heal by second intention, it is also packed with sterile moist gauze and covered with a sterile dressing. The American College of Surgeons, CDC, and others have recommended using sterile gloves and equipment (sterile technique) when changing dressings on any type of surgical incision.<sup>180,395-397</sup>

##### b. Discharge planning

In current practice, many patients are discharged very soon after their operation, before surgical incisions have fully healed.<sup>398</sup> The lack of optimum protocols for home incision care dictates that much of what is done at home by the patient, family, or home care agency practitioners must be individualized. The intent of discharge planning is to maintain integrity of the healing incision, educate the patient about the signs and symptoms of infection, and advise the patient about whom to contact to report any problems.

#### F. SSI SURVEILLANCE

Surveillance of SSI with feedback of appropriate data to surgeons has been shown to be an important component of strategies to reduce SSI risk.<sup>16,399,400</sup> A successful surveillance program includes the use of epidemiologically sound infection definitions (Tables 1 and 2) and effective surveillance methods, stratification of SSI rates according to risk factors associated with SSI development, and data feedback.<sup>25</sup>

##### 1. SSI risk stratification

###### a. Concepts

Three categories of variables have proven to be reliable predictors of SSI risk: (1) those that estimate the intrinsic degree of microbial contamination of the surgical site, (2) those that measure the duration of an operation,

and (3) those that serve as markers for host susceptibility.<sup>25</sup> A widely accepted scheme for classifying the degree of intrinsic microbial contamination of a surgical site was developed by the 1964 NAS/NRC Cooperative Research Study and modified in 1982 by CDC for use in SSI surveillance (Table 7).<sup>2,94</sup> In this scheme, a member of the surgical team classifies the patient's wound at the completion of the operation. Because of its ease of use and wide availability, the surgical wound classification has been used to predict SSI risk.<sup>16,94,126,401-405</sup> Some researchers have suggested that surgeons compare clean wound SSI rates with those of other surgeons.<sup>16,399</sup> However, two CDC efforts—the SENIC Project and the NNIS system—incorporated other predictor variables into SSI risk indices. These showed that even within the category of clean wounds, the SSI risk varied by risk category from 1.1% to 15.8% (SENIC) and from 1.0% to 5.4% (NNIS).<sup>125,126</sup> In addition, sometimes an incision is incorrectly classified by a surgical team member or not classified at all, calling into question the reliability of the classification. Therefore, reporting SSI rates stratified by wound class alone is not recommended.

Data on 10 variables collected in the SENIC Project were analyzed by using logistic regression modeling to develop a simple additive SSI risk index.<sup>125</sup> Four of these were found to be independently associated with SSI risk: (1) an abdominal operation, (2) an operation lasting >2 hours, (3) a surgical site with a wound classification of either contaminated or dirty/infected, and (4) an operation performed on a patient having ≥3 discharge diagnoses. Each of these equally weighted factors contributes a point when present, such that the risk index values range from 0 to 4. By using these factors, the SENIC index predicted SSI risk twice as well as the traditional wound classification scheme alone.

The NNIS risk index is operation-specific and applied to prospectively collected surveillance data. The index values range from 0 to 3 points and are defined by three independent and equally weighted variables. One point is scored for each of the following when present: (1) American Society of Anesthesiologists (ASA) Physical Status Classification of >2 (Table 10), (2) either contaminated or dirty/infected wound classification (Table 7), and (3) length of operation >T hours, where T is the approximate 75th percentile of the duration of the specific operation being performed.<sup>126</sup> The ASA class replaced discharge diagnoses of the SENIC risk index as a surrogate for the patient's underlying severity of illness (host susceptibility)<sup>406,407</sup> and has the advantage of being readily available in the chart during the patient's hospital stay. Unlike SENIC's constant 2-hour cut-point for duration of operation, the operation-specific cut-points used in the NNIS risk index increase its discriminatory power compared to the SENIC index.<sup>126</sup>

**b. Issues**

Adjustment for variables known to confound rate estimates is critical if valid comparisons of SSI rates are to be made between surgeons or hospitals.<sup>408</sup> Risk stratification, as described above, has proven useful for this purpose, but relies on the ability of surveillance personnel to find and record data consistently and correctly. For the three variables used in the NNIS risk index, only one study has focused on how accurately any of them are recorded. Cardo et al. found that surgical team members' accuracy in assessing wound classification for general and trauma surgery was 88% (95% CI: 82%-94%).<sup>409</sup> However, there are sufficient ambiguities in the wound class definitions themselves to warrant concern about the reproducibility of Cardo's results. The accuracy of recording the duration of operation (i.e., time from skin incision to skin closure) and the ASA class has not been studied. In an unpublished report from the NNIS system, there was evidence that overreporting of high ASA class existed in some hospitals. Further validation of the reliability of the recorded risk index variables is needed.

Additionally, the NNIS risk index does not adequately discriminate the SSI risk for all types of operations.<sup>27,410</sup> It seems likely that a combination of risk factors specific to patients undergoing an operation will be more predictive. A few studies have been performed to develop procedure-specific risk indices<sup>218,411-414</sup> and research in this area continues within CDC's NNIS system.

**2. SSI surveillance methods**

SSI surveillance methods used in both the SENIC Project and the NNIS system were designed for monitoring inpatients at acute-care hospitals. Over the past decade, the shift from inpatient to outpatient surgical care (also called ambulatory or day surgery) has been dramatic. It has been estimated that 75% of all operations in the United States will be performed in outpatient settings by the year 2000.<sup>4</sup> While it may be appropriate to use common definitions of SSI for inpatients and outpatients,<sup>415</sup> the types of operations monitored, the risk factors assessed, and the case-finding methods used may differ. New predictor variables may emerge from analyses of SSIs among outpatient surgery patients, which may lead to different ways of estimating SSI risk in this population.

The choice of which operations to monitor should be made jointly by surgeons and infection control personnel. Most hospitals do not have the resources to monitor all surgical patients all the time, nor is it likely that the same intensity of surveillance is necessary for certain low-risk procedures. Instead, hospitals should target surveillance efforts toward high-risk procedures.<sup>416</sup>

**a. Inpatient SSI surveillance**

Two methods, alone or together, have been used to identify inpatients with SSIs: (1) direct observation of the

**Table 10.** Physical Status Classification, American Society of Anesthesiologists\*

Code	Patient's Preoperative Physical Status
1	Normally healthy patient
2	Patient with mild systemic disease
3	Patient with severe systemic disease that is not incapacitating
4	Patient with an incapacitating systemic disease that is a constant threat to life
5	Moribund patient who is not expected to survive for 24 hours with or without operation

\*Reference 406.

Note: The above is the version of the ASA Physical Status Classification System that was current at the time of development of, and still is used in, the NNIS Risk Index. Meanwhile, the American Society of Anesthesiologists has revised their classification system; the most recent version is available at [http://www.asahq.org/profinfo/physical\\_status.html](http://www.asahq.org/profinfo/physical_status.html).

surgical site by the surgeon, trained nurse surveyor, or infection control personnel<sup>116,97,399,402,409,417-420</sup> and (2) indirect detection by infection control personnel through review of laboratory reports, patient records, and discussions with primary care providers.<sup>15,84,399,402,404,409,418,421-427</sup> The surgical literature suggests that direct observation of surgical sites is the most accurate method to detect SSIs, although sensitivity data are lacking.<sup>16,399,402,417,418</sup> Much of the SSI data reported in the infection control literature has been generated by indirect case-finding methods,<sup>125,126,422,425,426,428-430</sup> but some studies of direct methods also have been conducted.<sup>97,409</sup> Some studies use both methods of detection.<sup>84,409,424,427,431</sup> A study that focused solely on the sensitivity and specificity of SSIs detected by indirect methods found a sensitivity of 83.8% (95% CI: 75.7%-91.9%) and a specificity of 99.8% (95% CI: 99%-100%).<sup>409</sup> Another study showed that chart review triggered by a computer-generated report of antibiotic orders for post-cesarean section patients had a sensitivity of 89% for detecting endometritis.<sup>432</sup>

Indirect SSI detection can readily be performed by infection control personnel during surveillance rounds. The work includes gathering demographic, infection, surgical, and laboratory data on patients who have undergone operations of interest.<sup>433</sup> These data can be obtained from patients' medical records, including microbiology, histopathology, laboratory, and pharmacy data; radiology reports; and records from the operating room. Additionally, inpatient admissions, emergency room, and clinic visit records are sources of data for those postdischarge surgical patients who are readmitted or seek follow-up care.

The optimum frequency of SSI case-finding by either method is unknown and varies from daily to  $\leq 3$  times per week, continuing until the patient is discharged from the hospital. Because duration of hospitalization is often very short, postdischarge SSI surveillance has

become increasingly important to obtain accurate SSI rates (refer to "Postdischarge SSI Surveillance" section).

To calculate meaningful SSI rates, data must be collected on all patients undergoing the operations of interest (i.e., the population at risk). Because one of its purposes is to develop strategies for risk stratification, the NNIS system collects the following data on all surgical patients surveyed: operation date; NNIS operative procedure category;<sup>434</sup> surgeon identifier; patient identifier; age and sex; duration of operation; wound class; use of general anesthesia; ASA class; emergency; trauma; multiple procedures; endoscopic approach; and discharge date.<sup>433</sup> With the exception of discharge date, these data can be obtained manually from operating room logs or be electronically downloaded into surveillance software, thereby substantially reducing manual transcription and data entry errors.<sup>433</sup> Depending on the needs for risk-stratified SSI rates by personnel in infection control, surgery, and quality assurance, not all data elements may be pertinent for every type of operation. At minimum, however, variables found to be predictive of increased SSI risk should be collected (refer to "SSI Risk Stratification" section).

#### **b. Postdischarge SSI surveillance**

Between 12% and 84% of SSIs are detected after patients are discharged from the hospital.<sup>98,337,402,428,435-454</sup> At least two studies have shown that most SSIs become evident within 21 days after operation.<sup>446,447</sup> Since the length of postoperative hospitalization continues to decrease, many SSIs may not be detected for several weeks after discharge and may not require readmission to the operating hospital. Dependence solely on inpatient case-finding will result in underestimates of SSI rates for some operations (e.g., coronary artery bypass graft) (CDC/NNIS system, unpublished data, 1998). Any comparison of SSI rates must take into account whether case-finding included SSIs detected after discharge. For comparisons to be valid, even in the same institution over time, the postdischarge surveillance methods must be the same.

Postdischarge surveillance methods have been used with varying degrees of success for different procedures and among hospitals and include (1) direct examination of patients' wounds during follow-up visits to either surgery clinics or physicians' offices,<sup>150,399,402,404,430,436,440,441,447,452,455</sup> (2) review of medical records of surgery clinic patients,<sup>404,430,439</sup> (3) patient surveys by mail or telephone,<sup>435,437,438,441,442,444,445,448,449,455-457</sup> or (4) surgeon surveys by mail or telephone.<sup>98,428,430,437-439,443,444,446,448,450,451,455</sup> One study found that patients have difficulty assessing their own wounds for infection

(52% specificity, 26% positive predictive value),<sup>458</sup> suggesting that data obtained by patient questionnaire may inaccurately represent actual SSI rates.

Recently, Sands et al. performed a computerized search of three databases to determine which best identified SSIs: ambulatory encounter records for diagnostic, testing, and treatment codes; pharmacy records for specific antimicrobial prescriptions; and administrative records for rehospitalizations and emergency room visits.<sup>446</sup> This study found that pharmacy records indicating a patient had received antimicrobial agents commonly used to treat soft tissue infections had the highest sensitivity (50%) and positive predictive value (19%), although even this approach alone was not very effective.

As integrated health information systems expand, tracking surgical patients through the entire course of care may become more feasible, practical, and effective. At this time, no consensus exists on which postdischarge surveillance methods are the most sensitive, specific, and practical. Methods chosen will necessarily reflect the hospital's unique mix of operations, personnel resources, and data needs.

#### **c. Outpatient SSI surveillance**

Both direct and indirect methods have been used to detect SSIs that complicate outpatient operations. One 8-year study of operations for hernia and varicose veins used home visits by district health nurses combined with a survey completed by the surgeon at the patient's 2-week postoperative clinic visit to identify SSIs.<sup>459</sup> While ascertainment was essentially 100%, this method is impractical for widespread implementation. High response rates have been obtained from questionnaires mailed to surgeons (72%–90%).<sup>443,444,446,455,459-461</sup> Response rates from telephone questionnaires administered to patients were more variable (38%,<sup>444</sup> 81%,<sup>457</sup> and 85%<sup>455</sup>), and response rates from questionnaires mailed to patients were quite low (15%<sup>455</sup> and 33%<sup>446</sup>). At this time, no single detection method can be recommended. Available resources and data needs determine which method(s) should be used and which operations should be monitored. Regardless of which detection method is used, it is recommended that the CDC NNIS definitions of SSI (Tables 1 and 2) be used without modification in the outpatient setting.

### **G. GUIDELINE EVALUATION PROCESS**

The value of the HICPAC guidelines is determined by those who use them. To help assess that value, HICPAC is developing an evaluation tool to learn how guidelines meet user expectations, and how and when these guidelines are disseminated and implemented.

## II. Recommendations for prevention of surgical site infection

### A. RATIONALE

The Guideline for Prevention of Surgical Site Infection, 1999, provides recommendations concerning reduction of surgical site infection risk. Each recommendation is categorized on the basis of existing scientific data, theoretical rationale, and applicability. However, the previous CDC system for categorizing recommendations has been modified slightly.

Category I recommendations, including IA and IB, are those recommendations that are viewed as effective by HICPAC and experts in the fields of surgery, infectious diseases, and infection control. Both Category IA and IB recommendations are applicable for, and should be adopted by, all healthcare facilities; IA and IB recommendations differ only in the strength of the supporting scientific evidence.

Category II recommendations are supported by less scientific data than Category I recommendations; such recommendations may be appropriate for addressing specific nosocomial problems or specific patient populations.

No recommendation is offered for some practices, either because there is a lack of consensus regarding their efficacy or because the available scientific evidence is insufficient to support their adoption. For such unresolved issues, practitioners should use judgement to determine a policy regarding these practices within their organization. Recommendations that are based on federal regulation are denoted with an asterisk.

### B. RANKINGS

*Category IA.* Strongly recommended for implementation and supported by well-designed experimental, clinical, or epidemiological studies.

*Category IB.* Strongly recommended for implementation and supported by some experimental, clinical, or epidemiological studies and strong theoretical rationale.

*Category II.* Suggested for implementation and supported by suggestive clinical or epidemiological studies or theoretical rationale.

*No recommendation; unresolved issue.* Practices for which insufficient evidence or no consensus regarding efficacy exists.

Practices required by federal regulation are denoted with an asterisk (\*).

### C. RECOMMENDATIONS

#### 1. Preoperative

##### a. Preparation of the patient

1. Whenever possible, identify and treat all infections remote to the surgical site before elective operation and postpone elective operations on patients with remote site infections until the infection has resolved. *Category IA*
2. Do not remove hair preoperatively unless the hair at or around the incision site will interfere with the operation. *Category IA*
3. If hair is removed, remove immediately before the operation, preferably with electric clippers. *Category IA*
4. Adequately control serum blood glucose levels in all diabetic patients and particularly avoid hyperglycemia perioperatively. *Category IB*
5. Encourage tobacco cessation. At minimum, instruct patients to abstain for at least 30 days before elective operation from smoking cigarettes, cigars, pipes, or any other form of tobacco consumption (e.g., chewing/dipping). *Category IB*
6. Do not withhold necessary blood products from surgical patients as a means to prevent SSI. *Category IB*
7. Require patients to shower or bathe with an antiseptic agent on at least the night before the operative day. *Category IB*
8. Thoroughly wash and clean at and around the incision site to remove gross contamination before performing antiseptic skin preparation. *Category IB*
9. Use an appropriate antiseptic agent for skin preparation (Table 6). *Category IB*
10. Apply preoperative antiseptic skin preparation in concentric circles moving toward the periphery. The prepared area must be large enough to extend the incision or create new incisions or drain sites, if necessary. *Category II*
11. Keep preoperative hospital stay as short as possible while allowing for adequate preoperative preparation of the patient. *Category II*
12. No recommendation to taper or discontinue systemic steroid use (when medically permissible) before elective operation. *Unresolved issue*

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13. No recommendation to enhance nutritional support for surgical patients solely as a means to prevent SSI. *Unresolved issue*
14. No recommendation to preoperatively apply mupirocin to nares to prevent SSI. *Unresolved issue*
15. No recommendation to provide measures that enhance wound space oxygenation to prevent SSI. *Unresolved issue*

**b. Hand/forearm antisepsis for surgical team members**

1. Keep nails short and do not wear artificial nails. *Category IB*
2. Perform a preoperative surgical scrub for at least 2 to 5 minutes using an appropriate antiseptic (Table 6). Scrub the hands and forearms up to the elbows. *Category IB*
3. After performing the surgical scrub, keep hands up and away from the body (elbows in flexed position) so that water runs from the tips of the fingers toward the elbows. Dry hands with a sterile towel and don a sterile gown and gloves. *Category IB*
4. Clean underneath each fingernail prior to performing the first surgical scrub of the day. *Category II*
5. Do not wear hand or arm jewelry. *Category II*
6. No recommendation on wearing nail polish. *Unresolved Issue*

**c. Management of infected or colonized surgical personnel**

1. Educate and encourage surgical personnel who have signs and symptoms of a transmissible infectious illness to report conditions promptly to their supervisory and occupational health service personnel. *Category IB*
2. Develop well-defined policies concerning patient-care responsibilities when personnel have potentially transmissible infectious conditions. These policies should govern (a) personnel responsibility in using the health service and reporting illness, (b) work restrictions, and (c) clearance to resume work after an illness that required work restriction. The policies also should identify persons who have the authority to remove personnel from duty. *Category IB*
3. Obtain appropriate cultures from, and exclude from duty, surgical personnel who have draining skin lesions until infection has been ruled out or personnel have received adequate therapy and infection has resolved. *Category IB*
4. Do not routinely exclude surgical personnel who are colonized with organisms such as *S. aureus* (nose, hands, or other body site) or group A *Streptococcus*, unless such personnel have been linked epidemiologically to dissemination of the organism in the healthcare setting. *Category IB*

**d. Antimicrobial prophylaxis**

1. Administer a prophylactic antimicrobial agent only when indicated, and select it based on its efficacy against the most common pathogens causing SSI for a specific operation (Table 4) and published recommendations.<sup>266,268,269,282-284</sup> *Category IA*
2. Administer by the intravenous route the initial dose of prophylactic antimicrobial agent, timed such that a bactericidal concentration of the drug is established in serum and tissues when the incision is made. Maintain therapeutic levels of the agent in serum and tissues throughout the operation and until, at most, a few hours after the incision is closed in the operating room. *Category IA*
3. Before elective colorectal operations in addition to d2 above, mechanically prepare the colon by use of enemas and cathartic agents. Administer non-absorbable oral antimicrobial agents in divided doses on the day before the operation. *Category IA*
4. For high-risk cesarean section, administer the prophylactic antimicrobial agent immediately after the umbilical cord is clamped. *Category IA*
5. Do not routinely use vancomycin for antimicrobial prophylaxis. *Category IB*

**2. Intraoperative****a. Ventilation**

1. Maintain positive-pressure ventilation in the operating room with respect to the corridors and adjacent areas. *Category IB*
2. Maintain a minimum of 15 air changes per hour, of which at least 3 should be fresh air. *Category IB*
3. Filter all air, recirculated and fresh, through the appropriate filters per the American Institute of Architects' recommendations.<sup>299</sup> *Category IB*
4. Introduce all air at the ceiling, and exhaust near the floor. *Category IB*
5. Do not use UV radiation in the operating room to prevent SSI. *Category IB*
6. Keep operating room doors closed except as needed for passage of equipment, personnel, and the patient. *Category IB*
7. Consider performing orthopedic implant operations in operating rooms supplied with ultraclean air. *Category II*
8. Limit the number of personnel entering the operating room to necessary personnel. *Category II*

**b. Cleaning and disinfection of environmental surfaces**

1. When visible soiling or contamination with blood or other body fluids of surfaces or equipment occurs during an operation, use an EPA-approved hospital disinfectant to clean the affected areas before the next operation. *Category IB\**

2. Do not perform special cleaning or closing of operating rooms after contaminated or dirty operations. *Category IB*
3. Do not use tacky mats at the entrance to the operating room suite or individual operating rooms for infection control. *Category IB*
4. Wet vacuum the operating room floor after the last operation of the day or night with an EPA-approved hospital disinfectant. *Category II*
5. No recommendation on disinfecting environmental surfaces or equipment used in operating rooms between operations in the absence of visible soiling. *Unresolved issue*

#### c. Microbiologic sampling

1. Do not perform routine environmental sampling of the operating room. Perform microbiologic sampling of operating room environmental surfaces or air only as part of an epidemiologic investigation. *Category IB*

#### d. Sterilization of surgical instruments

1. Sterilize all surgical instruments according to published guidelines.<sup>212,299,314,321</sup> *Category IB*
2. Perform flash sterilization only for patient care items that will be used immediately (e.g., to reprocess an inadvertently dropped instrument). Do not use flash sterilization for reasons of convenience, as an alternative to purchasing additional instrument sets, or to save time. *Category IB*

#### e. Surgical attire and drapes

1. Wear a surgical mask that fully covers the mouth and nose when entering the operating room if an operation is about to begin or already under way, or if sterile instruments are exposed. Wear the mask throughout the operation. *Category IB\**
2. Wear a cap or hood to fully cover hair on the head and face when entering the operating room. *Category IB\**
3. Do not wear shoe covers for the prevention of SSI. *Category IB\**
4. Wear sterile gloves if a scrubbed surgical team member. Put on gloves after donning a sterile gown. *Category IB\**
5. Use surgical gowns and drapes that are effective barriers when wet (i.e., materials that resist liquid penetration). *Category IB*
6. Change scrub suits that are visibly soiled, contaminated, and/or penetrated by blood or other potentially infectious materials. *Category IB\**
7. No recommendations on how or where to launder scrub suits, on restricting use of scrub suits to the operating suite, or for covering scrub suits when out of the operating suite. *Unresolved issue*

#### f. Asepsis and surgical technique

\*Federal regulation: OSHA

1. Adhere to principles of asepsis when placing intravascular devices (e.g., central venous catheters), spinal or epidural anesthesia catheters, or when dispensing and administering intravenous drugs. *Category IA*
2. Assemble sterile equipment and solutions immediately prior to use. *Category II*
3. Handle tissue gently, maintain effective hemostasis, minimize devitalized tissue and foreign bodies (i.e., sutures, charred tissues, necrotic debris), and eradicate dead space at the surgical site. *Category IB*
4. Use delayed primary skin closure or leave an incision open to heal by second intention if the surgeon considers the surgical site to be heavily contaminated (e.g., Class III and Class IV). *Category IB*
5. If drainage is necessary, use a closed suction drain. Place a drain through a separate incision distant from the operative incision. Remove the drain as soon as possible. *Category IB*

#### 3. Postoperative incision care

- a. Protect with a sterile dressing for 24 to 48 hours postoperatively an incision that has been closed primarily. *Category IB*
- b. Wash hands before and after dressing changes and any contact with the surgical site. *Category IB*
- c. When an incision dressing must be changed, use sterile technique. *Category II*
- d. Educate the patient and family regarding proper incision care, symptoms of SSI, and the need to report such symptoms. *Category II*
- e. No recommendation to cover an incision closed primarily beyond 48 hours, nor on the appropriate time to shower or bathe with an uncovered incision. *Unresolved Issue*

#### 4. Surveillance

- a. Use CDC definitions of SSI (Table 1) without modification for identifying SSI among surgical inpatients and outpatients. *Category IB*
- b. For inpatient case-finding (including readmissions), use direct prospective observation, indirect prospective detection, or a combination of both direct and indirect methods for the duration of the patient's hospitalization. *Category IB*
- c. When postdischarge surveillance is performed for detecting SSI following certain operations (e.g., coronary artery bypass graft), use a method that accommodates available resources and data needs. *Category II*
- d. For outpatient case-finding, use a method that accommodates available resources and data needs. *Category IB*
- e. Assign the surgical wound classification upon

- completion of an operation. A surgical team member should make the assignment. *Category II*
- f. For each patient undergoing an operation chosen for surveillance, record those variables shown to be associated with increased SSI risk (e.g., surgical wound class, ASA class, and duration of operation). *Category IB*
  - g. Periodically calculate operation-specific SSI rates stratified by variables shown to be associated with increased SSI risk (e.g., NNIS risk index). *Category IB*
  - h. Report appropriately stratified, operation-specific SSI rates to surgical team members. The optimum frequency and format for such rate computations will be determined by stratified case-load sizes (denominators) and the objectives of local, continuous quality improvement initiatives. *Category IB*
  - i. No recommendation to make available to the infection control committee coded surgeon-specific data. *Unresolved issue*

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## **C CONTINUING EDUCATION EXAMINATION ON THE "GUIDELINE FOR PREVENTION OF SURGICAL SITE INFECTION, 1999"**

The Centers for Disease Control and Prevention (CDC) is accredited as a provider of continuing education by the International Association for Continuing Education and Training (IACET) and the Accreditation Council for Continuing Medical Education (ACCME) and the American Nurses Credentialing Center's Commission on Accreditation. This learner-paced study package has been structured according to IACET's Criteria and Guidelines and ACCME's Essentials and Standards. The CDC designates this educational activity for a maximum of .15 continuing education units (CEUs), 1.5 category 1 credit (CME) toward the American Medical Association's Physician's Recognition Award, or 1.8 contact hours of continuing nurses education (CNE) credit.

### **INSTRUCTIONS FOR CREDIT**

1. To receive credit, read the objectives and guideline, then complete and return the examination answer form either electronically (<http://www.cdc.gov/ncidod/hip/>) or by post to: SSI Guideline Evaluation Activity, Hospital Infections Program, Mailstop E69, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Atlanta, GA 30333.
2. Allow 45 days for processing the application and awarding credit. A certificate of completion will be mailed to you.
3. There is no fee for participating in this activity.
4. The deadline for applying for CEU, CME, or CNE for this learning activity is April 15, 2000.

### **OBJECTIVES**

1. Describe the frequency of surgical site infections in hospitalized patients.
2. List the most frequently occurring pathogens associated with surgical site infections and list potential reservoirs of infection.
3. List three intrinsic factors associated with increased risk of surgical site infection.
4. Identify three preoperative practices that have been shown to reduce the risk of surgical site infection.
5. Identify three intraoperative practices that, although not proven, may reduce the risk of surgical site infection.
6. Define the criteria for surgical site infections used for surveillance purposes.
7. Describe inpatient, outpatient, and postdischarge methods of surgical site infection surveillance.
8. List three variables used to stratify the risks associated with development of surgical site infection.

### **EXAMINATION QUESTIONS (Circle the answer[s] on the answer form)**

#### **Part I.**

1. SSIs are the most frequently occurring nosocomial infection among all hospitalized patients. T F
2. Most SSIs are confined to the incision. T F
3. When an SSI contributes to a patient's death, it is usually a serious infection involving organs or spaces accessed during the operation. T F
4. According to NNIS system data, the most frequently isolated pathogens in rank order from SSI are:
  - a. *Escherichia coli*, *Klebsiella* spp., *Pseudomonas aeruginosa*, and coagulase-negative staphylococci
  - b. *Staphylococcus aureus*, coagulase-negative staphylococci, *Enterococcus* spp., and *Escherichia coli*
  - c. *Staphylococcus aureus*, *Enterococcus* spp., *Escherichia coli*, and *Pseudomonas aeruginosa*
  - d. *Klebsiella* spp., *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and coagulase-negative staphylococci
5. The risk of SSI is related to the interaction between the dose of bacterial contamination, the virulence of the organism, and the resistance of the host patient. T F
6. For most SSIs, which of the following is the primary source of pathogens
  - a. Operating room air
  - b. Surgical team members
  - c. Contaminated instruments
  - d. Patient's endogenous flora
7. Which of the following patient characteristics has been associated with increased SSI risk?
  - a. Obesity (>20% ideal body weight)
  - b. Coincident remote site infection
  - c. Cigarette smoking
  - d. All of the above
8. The association between SSI risk and receipt of steroids or immunosuppressive drugs is unresolved. T F
9. Preoperative antiseptic showering has been shown to reduce skin microbial colony counts and reduce SSI rates. T F
10. The surgical scrub must be performed for a duration of 10 minutes with an appropriate antiseptic. T F
11. Timing of antimicrobial prophylaxis should be such that an adequate bactericidal concentration of the drug is established in serum and tissues by the time the skin is incised. T F
12. Flash sterilization is acceptable for the routine reprocessing of surgical instruments that are in short supply. T F
13. Prophylactic antimicrobial agents should be extended for at least 72 hours postoperatively. T F
14. Operating rooms should be maintained at negative pressure with respect to corridors and adjacent areas. T F
15. An incision closed primarily should be protected with a sterile dressing for 24 to 48 hours postoperatively. T F
16. Surgical surveillance efforts should be targeted toward high-risk procedures. T F
17. Which of the following practices are identified as unresolved issues with respect to their potential for reducing SSI rates? (Select all that apply.)
  - a. Providing coded surgeon-specific data to the infection control committee
  - b. Covering a scrub suit when out of the operating suite
  - c. Using tacky mats at the entrance to the operating suite
  - d. Using ultraviolet radiation in the operating room
18. Which of the following practices is *not* considered good surgical technique?
  - a. Gentle handling of tissues
  - b. Maintaining effective hemostasis
  - c. Placing of a drain through the main surgical incision
  - d. Minimizing the amount of devitalized tissue
19. Infection control professionals should routinely assign the surgical wound classification. T F

**134 Continuing Education****ANSWER FORM**

Continuing Education Examination on the "Guideline for Prevention of Surgical Site Infection, 1999." There is no fee for applying for CEU, CME or CNE for this learning activity; deadline for application is April 15, 2000.

**Part I.**

- |            |            |         |             |
|------------|------------|---------|-------------|
| 1. T F     | 6. a b c d | 11. T F | 16. T F     |
| 2. T F     | 7. a b c d | 12. T F | 17. a b c d |
| 3. T F     | 8. T F     | 13. T F | 18. a b c d |
| 4. a b c d | 9. T F     | 14. T F | 19. T F     |
| 5. T F     | 10. T F    | 15. T F |             |

**Part II.**

The following questions will not be included in your examination score, but your answers are critical to help us evaluate who reads and implements the guideline.

20. Which of the following best describes your profession?

☐ Physician

Check one: ☐ Surgeon ☐ Anesthesiologist ☐ Infectious Disease  
☐ OB/GYN ☐ Other

☐ Infection Control Professional (includes Infection Control Nurse)

☐ Nurse

Check one: ☐ Operating Room Nurse ☐ Other

☐ Operating Room Technician

☐ Physician's Assistant

☐ Pharmacist

☐ Other (specify) \_\_\_\_\_

21. Are you responsible for managing surgical patients?

☐ Yes ☐ No

22. Are you responsible for developing policies for prevention and control of nosocomial surgical site infections?

☐ Yes ☐ No

23. Are you responsible for directing or performing surveillance of surgical site infections?

☐ Yes ☐ No

24. In which of the following settings do you perform the responsibilities identified in items 21 to 23 above? (Check all that apply)

☐ Hospital-based (Check all that apply): ☐ Inpatient surgery ☐ Outpatient surgery

☐ Free-standing surgery center

☐ Home care services

25. How long did it take you to complete this learning activity?

☐ Less than 90 minutes

☐ 90 minutes

☐ Greater than 90 minutes

**Part III.**

The following questions will not be included in your examination score, but will help us assess your perceptions of how well the learning objectives were met and how readable and easily understood the material was.

	1 Strongly Agree	2 Agree	3 Neither Agree nor Disagree	4 Disagree	5 Strongly Disagree
26. All learning objectives were relevant to the SSI Guideline.	1	2	3	4	5
27. I understood what the authors were trying to say.	1	2	3	4	5
28. I was able to interpret the tables and figure.	1	2	3	4	5
29. Overall, the presentation of the guideline enhanced my ability to read and understand it.	1	2	3	4	5

**APPLICATION FOR CONTINUING EDUCATION CREDIT**

Name: \_\_\_\_\_

Mailing address: \_\_\_\_\_

Daytime phone number: \_\_\_\_\_

Type of credit: ☐ CEU ☐ CME ☐ CNE

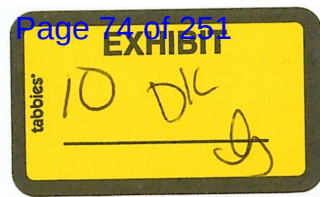
Date of application: \_\_\_\_\_

Signature: \_\_\_\_\_

Return to: SSI Guideline Evaluation, Hospital Infections Program/CDC, Mailstop E69, 1600 Clifton Road, NE, Atlanta, GA 30333.

# **EXHIBIT DX48**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS



# Hospitals Contemplate Airborne Infection

## HVAC Upgrades Part of Overall Strategy to Eliminate IAQ Issues

By Joanna R. Turpin  
Of The NEWS Staff

According to the Centers for Disease Control and Prevention (CDC), health care-associated infections (HAIs) are a major cause of morbidity and mortality in the U.S. In a 2011 survey of acute care hospitals, the CDC found that on any given day, about one in 25 hospital patients had at least one health care-associated infection and about 75,000 hospital patients with HAIs died during their hospitalizations. Considering this survey did not take into account HAIs found in other health care settings, such as ambulatory surgery (outpatient) clinics or long-term care facilities, and it is easy to see why infection control is receiving increased scrutiny by those working in the health care industry, as well as the federal government.

When an infection occurs in a health care facility, it is usually very difficult to determine where it came from, as sources may include medical instruments, patients, staff, visitors, as well as the airborne transmission of infectious agents. It is the last point that is of concern to HVAC professionals as they are often tasked with making sure the mechanical equipment is providing the cleanest possible air to the health care facility. This often includes upgrading a facility's HVAC systems to include advanced filtration, UV lights, precise temperature/humidity control, and proper pressurization.

### HVAC and HAIs

As noted in ASHRAE's "HVAC Design Manual for Hospitals and Clinics - 2013," the nature of infectious pathogens, the modes of transmission, the causation of infections, and their relationship to HVAC system design are complicated and not fully understood. But, most agree about 90 percent of HAIs are transmitted by direct contact, with about 10 percent resulting from airborne transmission.

"Everyone seems to agree that the percentage of airborne infections is still pretty low, but even in the 10-15 percent range, is that acceptable? I think the threshold for acceptance has gone down," said Dan Koenigshofer, vice president of health care engineering, Dewberry, Chapel Hill, North Carolina. "One of the biggest sources of surgical site infections (SSIs) is thought to be skin particles. You can put the cleanest air in the



As part of an overall strategy, hospitals are starting to replace equipment — such as this rusted air handling unit — in order to reduce HAIs. (Feature Photos on this page courtesy of Dan Koenigshofer, Dewberry)



Proper service and maintenance practices at hospitals may help uncover various hidden problems such as this coil frame, which is completely rusted through.



Deteriorating fiberglass lining in air handling units and ductwork is driving a lot of replacement work in hospitals and other health care settings.

world in the room, but if skin particles are falling off the doctors and nurses into the surgical site, that's a problem that can't be solved by the HVAC system. At about 10 microns, skin particles are affected by gravity and will not be swept away by the airflow."

One way to fix this problem is to make operating rooms run the same way that cleanrooms do, said Koenigshofer. "Why are we more worried about our wafers than our grandmothers? We should be building cleanroom-level HVAC systems for operating rooms, and the medi-

cal staff should be gowning up in bunny suits. If we can make cleanrooms really clean, we can make operating rooms really clean."

That is not likely to happen any time soon, but health care facilities are interested in making other upgrades to their HVAC systems to help mitigate airborne infections. "We are putting UV lights in, just about every air-handling unit," said Koenigshofer. "There are also heightened concerns about filter quality and making sure the racks are tight and have no holes. Filter

racks should be sufficiently rigid so they don't bend with pressure drop across them. And magnehelic gauges should be used, so filters are changed based on the pressure drop across them, rather than the calendar. The CDC recommends final filters be downstream of humidifiers, so we prefer to place humidifiers in the air-handling unit. There, they are also easier to maintain and control than in the ductwork near the operating rooms."

Low-efficiency filtration and filter bypass can be issues with any

airborne transmission of infectious agents that may lead to HAIs, which is why some hospitals are approaching the issue more aggressively, said Brent Stephens, Department of Civil, Architectural, and Environmental Engineering, Illinois Institute of Technology in Chicago.

As an example, Stephens points to a hospital he recently worked on that used a series of particle filters, starting with MERV 7 and MERV 13 on the return side (mixed with outside air) and HEPA filtration on the supply side of the HVAC systems serving patient rooms. "There is a long-standing notion that HEPA will have higher pressure drop and increased fan energy use when used in a variable air volume (VAV) system, but this particular hospital was designed in an aggressive way to reduce the risk of transmitting particles from one room to another via the ventilation system. They also had quite high air-exchange rates and total airflow rates relative to the room volumes — higher than what is required by ASHRAE standards."

"In addition to making sure the correct air changes per hour are taking place, it is important for hospitals to maintain precise levels of temperature and humidity," said André LeBlanc, director of operations, ConEdison Solutions, Tampa, Florida, who regularly helps hospitals upgrade their HVAC systems in order to reduce infection risk. "Once you get relative humidity levels above 65 per-

# focus

cent or below 20 percent, your infectious control rates or complications related to the environment go way up. I see a lot of humidity problems in older hospitals, in particular, where little attention was given to the infrastructure."

Another reason why hospitals experience so many problems with humidity, said LeBlanc, is that sensors are not regularly checked to make sure they are working properly. "It really has to start with the engineers specifying the correct types of accurate devices and then making sure those devices are actually installed. It's really common to use relative humidity sensors that are between 3 and 5 percent accuracy, and, a lot of times, I'll find those sensors are not even that accurate. They drift over time, and they're not replaced."

Commissioning could help with this issue, said LeBlanc, but

it rarely happens the way it should, especially in retrofit projects. "If you're building a hospital or a wing from the ground up, retrofit jobs have a tendency to not be inclusive of commissioning. You need to look at continuous commissioning to make sure that, over time, the useful operational life of the equipment is operating as it was intended within the parameters that it was designed within. I don't see that happening very often at all."

Proper pressurization is another concern in terms of infection control, particularly in sterile processing departments, which is where instruments are decontaminated, sterilized, and then packed for use.

"Getting the pressurization correct is very important because they're bringing in contaminated instruments into a space that should be highly negative," said Koenigshofer. "This negative space is situ-

ated right next to a positive space, and there are cart washers, sterilizers, and maybe even a window or door between the spaces, so it's hard to maintain pressurization, low temperatures, and low humidity."

In situations such as these, Koenigshofer advises hospitals to install canopy hoods over the cart washers and sterilizers in order to remove the heat and humidity generated by the sterilizing process. "We need to get the hot and humid air out right away, rather than try to overpower it with supply air. You need to calculate the supply and exhaust airflows needed to get sufficient offsets in order to get a pressure differential, then a testing and balancing company can come in and set it up."

## UVc and More

While new technologies have emerged to help reduce rates of



Portable UV disinfection systems, such as the Germ-Zapping Robots from Xenex, are gaining in popularity.

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## UV System Keeps Germs Away


**G**eary Community Hospital in Junction City, Kansas, recently underwent a \$34 million expansion that included the addition of a 15,000-square-foot surgery suite. The HVAC system for this suite is comprised of a conventional four-pipe chiller and boiler loop concept and UV germicidal irradiation (UVGI) lamps in each of the five air handlers.

The Fresh-Aire UV Commercial Series UVGI systems use 32-inch-long UV lamps in modular racks affixed to the supply side of every coil. UVGI alters the DNA and disables the reproductive capabilities of any microbe passing through its UV field in the air handler. Microbes later become entrapped in each unit's HEPA filters, which are manufactured by Camfil Farr. Combined with each air handler's 30 percent pre-filter and 65 percent filter, the HEPA filters deliver 99.9 percent particle-free filtration, providing optimum IAQ.



Gearry Community Hospital's \$34 million expansion included the addition of a 15,000-square-foot surgery suite. (Photo courtesy of Geary Community Hospital)

By disinfecting the air conditioning coils, condensate drain pans, interior HVAC unit surfaces, and the supply air from microbial contaminants, UV systems also help reduce maintenance costs and improve energy efficiency, noted reps with Fresh-Aire UV. The company stated that industry studies show coils void of biological growth have unrestricted static pressure, reduced blower electric load, and optimum heat transfer. And that even a thin growth of bio-film on coil surfaces can reduce the free area and increase air velocity up to 9 percent.

According to system designer, Shane Lutz, principal, Henderson Engineers, "We've seen the effects of no UV lights in older HVAC systems, and there's a tendency for coil microorganism growth that you definitely wouldn't want distributed throughout a critical environment such as an operating room or any other health care environment." 

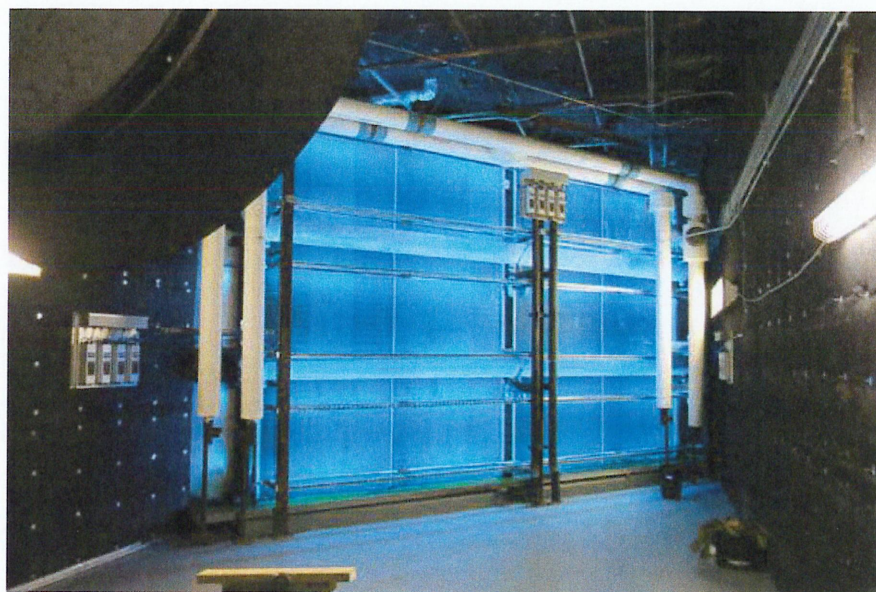
# focus

infection, hospitals are not always eager to implement them, particularly in older facilities. UV lights are a perfect example, as they have been broadly accepted for the last decade, but LeBlanc noted he still does not see them installed in the majority of hospitals in his area.

"The reason is cost. A lot of times we're dealing with hospitals that have old air-handling units, so

UV lights aren't even considered until it's time to replace the equipment. And it's too bad, because they really work well," LeBlanc said. "Unfortunately, health care is an industry that is primarily driven by a first-cost mentality."

Portable UV disinfection systems such as the Germ-Zapping Robots™ from Xenex are also gaining in popularity, said Stephens.



By disinfecting the air conditioning coils, condensate drain pans, and the supply air from microbial contaminants, UV systems can help reduce maintenance costs and improve energy efficiency. (Photo courtesy of Fresh-Aire UV)

These systems use patented pulsed xenon UV light designed to destroy harmful bacteria, viruses, fungi, and bacterial spores in any location within a hospital, from operating rooms to isolation rooms to offices and utility rooms. The Xenex germ-zapping robot can disinfect a typical patient or procedure room in five to 10 minutes.

Xenex robots use xenon (not mercury) to create UV light, and, according to the company, its patented technology is 25,000 times more intense than mercury UV

systems. Pulsed xenon emits high-intensity UV light across a broad germicidal spectrum (200-280 nanometers versus the single spectrum of 253.7 nanometers for mercury bulbs), which enables Xenex devices to eliminate a wider range of pathogens at a much faster rate than mercury devices.

David N. Schurk, director of health care accounts, Heat Transfer Solutions, an independent manufacturer's representative in Houston, is particularly excited about the needlepoint bipolar

ionization systems from Global Plasma Solutions (GPS), which use a plasma field to break down harmful gases, fibers, bacteria, and allergens into simple, safe, and naturally occurring molecules.

"I strongly promote these systems because they perform multiple duties," said Schurk. "First, they keep the coil clean. We mount the system on the entering air side of the cooling coil, so the air is basically being sterilized before it enters the coil. That keeps the coil clean from front to back. Second, if there is no downstream filtration, the system will keep the rest of the air handler and ductwork clean and ions can flow into the space and mix with the room air, so it can keep surfaces clean."

The GPS system costs about twice as much as UV lights, but Schurk noted it uses less electricity and requires less maintenance as there are no bulbs to replace. Some hospitals have already installed the GPS system, but most are still researching the technology and waiting to learn more about its long-term impact. "Hospitals are not pioneers — there are very few of them that are willing to embrace the latest and greatest of anything until it's been vetted and tested. Most of the 'latest technologies' employed today had been implemented commercially for five to 10 years already."

While it is likely a very small percentage of HAIs can be attributed to HVAC systems, hospitals are increasingly looking for ways to reduce that risk even further. Advanced filtration, UV lights, and precise temperature/humidity controls are just a few of the upgrades hospitals are looking to incorporate as part of an overall strategy aimed at reducing rates of infection. **N**

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# **EXHIBIT DX49**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS

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MICHAEL WAYNE BUCK  
UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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In re Bair Hugger Forced  
Air Warming Products  
Liability Litigation

MDL No. 15-2666 (JNE/FLN)  
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Minneapolis, MN  
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VIDEOTAPED DEPOSITION OF  
MICHAEL WAYNE BUCK  
-----

Job No. 124783

Taken June 7, 2017

By Cynthia Kirsch

MICHAEL WAYNE BUCK

A No.

Q No. 18 asks for any communications, including e-mails, between you and some of Scott Augustine's family members; Brent Augustine, Sue Augustine, Garrett Augustine, Ryan, or any other agent or employee of Augustine.

Any communications responsive?

A No.

Q 19 asked for study -- any study, test, trial, experiment, research or data analysis that you sponsored, conducted, performed.

And I know what we have with respect to your expert report, but beyond your expert report, do you have any other study or test or experiment or research that you performed on the Bair Hugger?

A No.

Q 20 asked for any communications or documents that you either sent to or received from any forced-air warming manufacturer.

Any responsive documents?

A No.

Q I understand you have a B.A. in biology; correct?

A Yes.

MICHAEL WAYNE BUCK

Q You received that in 1989?

A Yes.

Q Do you have any degree beyond your Bachelor of Arts?

A No.

Q Do you have any extra training, extra courses in microbiology?

A I've taken a graduate environmental microbiology course from Dr. Vesley through my time at the university.

Q How many course hours was that one course?

A It was either three or four credits, class and lab.

Q What did that class or lab --

A Class and lab, I should say; combined.

Q What did that course include?

A Lecture, environmental microbiology principles; and then the lab work was completing designed lab exercises that were provided by the instructor that were completed by students with reports for each experiment or each exercise.

Q Was that a part of your B.A. degree?

A No.

Q Afterwards?

MICHAEL WAYNE BUCK

A Yes.

Q When did you take this course?

A It would have been sometime in the mid-90s or -- early to mid-90s.

Q Do you hold yourself out as a microbiologist?

A No.

Q You don't hold yourself out as an expert in microbiology?

A No.

Q I don't notice from your CV that you've given any presentations on microbiology or bacteria; is that correct?

A Yes, that's correct.

Q Is it also correct you have not written any articles about microbiology or bacteria; correct?

A Correct.

Q Do you have any special training or courses in aerobiology?

A I did take -- I forget the exact description of the class -- but I did take Dr. Vincent's class that dealt with ventilation. And he used a book that dealt with those principles. Yes.

Q One course you took?

MICHAEL WAYNE BUCK

A Yes.

Q When was that?

A Same time frame.

Q Mid-90s?

A Yes.

Q Do you hold yourself out as an expert in aerobiology?

A No.

Q Do you have any specialized training in filtration?

A No.

Q You don't hold yourself out as an expert in filtration?

A No.

Q Are you a member of ASHRAE?

A I am not.

Q Do you know what ASHRAE is?

A I do.

Q Have you followed any ASHRAE standards in any work that you do?

A Yes. There are certain principles or guidelines in ASHRAE that are followed.

Q Which standards are you familiar with that you might follow?

MICHAEL WAYNE BUCK

A Some of the ASHRAE ventilation standards for specialty care environments in a hospital.

Q Do you know which standards you're referring to?

A Not off the top of my head, but -- I think 152 is a ventilation standard. I'd have to look it up.

Q Any other standards that you follow?

A Not that I can think of off the top of my head. No.

Q Any specialized training or courses in heat transfer?

A No.

Q Do you hold yourself out as an expert in heat transfer?

A No.

Q Have you been involved in any clinical trials?

A No.

Q Any specialized training in infectious diseases?

A No.

Q Do you hold yourself out as an expert on infectious diseases?

MICHAEL WAYNE BUCK

A No.

Q Do you hold yourself out as an expert on surgical site infections?

A No.

Q Have you ever been involved in or consulted with a manufacturer on patient warming devices?

A No.

Q Before being retained in this lawsuit, have you ever contacted a device manufacturer concerning patient warming devices?

A No.

Q Is it true that most of the experience that you have, based on your CV, deals with asbestos, lead, and water intrusion issues?

A I don't know if I would say "most." My asbestos experience goes from 1989 to 1999. From that point forward, I have been involved in indoor air quality. Most of that work has involved water management or water damage in buildings as a result of that.

But in addition to that, I've also done work or completed work in the hospital in that regard as well, in addition to doing general routine or routine types of hospital environment checks in the

MICHAEL WAYNE BUCK

hospital.

Q Give it -- give me an example.

A Monitoring pressure, doing particle counts in specialty care areas, operating rooms, bone marrow transplant rooms, those types of things, checking pressure management in operating rooms with handheld devices such -- like a handheld digital pressure gauge, those types of activities.

Q You mentioned particle counting. For what hospitals have you been asked to do particle counting?

A Well, the University of Minnesota, a hospital, Fairview, Fairview Riverside. That is part of my job. When they have a concern or an issue that comes up, they would call and ask us to evaluate a space, and we would do that.

Q And --

A Either Andy or myself or both of us.

Q And they would ask you to do what with respect to the space?

A Verify environmental conditions to make sure that the space was performing or that it was -- expectations were met as far as pressure management issues.

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Q Meaning maintaining positive pressure in a particular room compared to another room?

A Correct.

Q Have you been asked, with respect to Fairview, to do any particle counting in its operating room?

A We have from time to time done particle counting and pressure checks in the operating rooms at Fairview, yes.

Q How many times?

A Over -- since 1999. I couldn't come up with a number for you other than to say several.

Q Any other hospital that has asked you to do particle counting?

A Specifically particle counting --

Q Yes.

A -- or particle counting as part of my work in that hospital that I did as a result of verifying environmental conditions?

Q What would be the difference?

A I'm asking.

Q I just want to -- at this point I'm talking about particle counting.

Has any other hospital asked you to come in

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Q Do you agree that particles have to be a certain size to carry bacteria?

MS. ZIMMERMAN: Object to form.

THE WITNESS: Yes.

BY MS. LEWIS:

Q One of the figures in your report has the diagram about the various sizes of bacteria, is that right, Figure 1?

A Yes. That was a table that was included.

Q Where did you get that figure from?

A Pardon me?

Q Where did you get the chart from, Figure 1?

A I believe it was from a operating room photograph or picture that was obtained.

Q You mentioned staph aureus on page 6 of your report, and you mentioned that staph aureus has the size of .9 microns; correct?

A Yes.

Q Do you also have an understanding that bacteria doesn't -- a cell of bacteria doesn't travel by itself?

MS. ZIMMERMAN: Object to form.

THE WITNESS: That's -- I've read that in

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certain articles, yes.

BY MS. LEWIS:

Q Do you have a reason to disagree with it?

A I do not.

Q What's your understanding of how large a particle needs to be to carry bacteria?

A I don't specifically know how large a particle has to be to carry bacteria.

Q Have you seen sources that say particles that are capable of carrying bacteria are between 4 and 20 microns?

A I have seen that written in literature, yes.

Q Do you have a reason to disagree with that?

A I do not.

Q Based on the resource where you found that statement, and based on your Figure 2 where you list staph aureus being a -- 0.9 micron in size, you would agree that a particle the size of .3, for example, would not contain a cell of staph aureus?

A I don't know that for sure, but based on what's included in the diagram, that would make sense.

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Q Do you agree that all bacteria that might be in the air or on a surface might not even be viable?

A That could be possible. Particles in the air are viable and non-viable.

Q Is there a way to detect whether it's viable or not viable from a particle counter?

A The particle counter measures all the particles that come into the counter and treats them as particles counted.

Q The particle counter doesn't make a distinction as to what that particle is; correct?

A Correct.

Q The particle counter doesn't say what's contained on that particle; correct?

A Correct. It counts the total number of particles or however the machine is set up.

Q The particle counter doesn't differentiate whether it's a dust particle or a skin squame or some other type of particle; correct?

A Yes, that's correct.

Q The particle counter doesn't detect bacteria; correct?

A The particle counter corrects particles -- it collects particles. It doesn't detect bacteria.

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It collects particles or detects particles. It counts particles in the air.

Q Do you have any knowledge based on what you do for hospitals whether disinfectants, if used to wipe down a surface or is used to wipe up a floor, does that reduce the number of particles?

A On the surface?

Q Yes.

A That's been cleaned?

Q With a disinfectant.

MS. ZIMMERMAN: Object to form.

THE WITNESS: I've read in the literature that that is true, yes. And we have also sampled rooms that have been cleaned or terminally cleaned, depending on the description of the cleaning service, and found that there can be a reduction based on the ability or the -- how well the room is cleaned, yes.

BY MS. LEWIS:

Q Humans also -- we shed particles; right?

A Yes.

Q Or particles shed from clothes?

A Yes.

Q If an OR is cleaned with a disinfectant before a surgery starts and the surfaces are cleaned

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Q -- to assist him; correct?

MS. ZIMMERMAN: Object to form.

THE WITNESS: To work with me, to work together, yes.

BY MS. LEWIS:

Q What did Andy tell you?

A Andy asked me if I would be interested in helping him evaluate a piece of equipment for a law firm.

Q He gave more details, what the equipment was, and why?

A Not at that -- not initially. He just asked for my availability and my willingness to participate, and that was the initial talk that we had.

Q Was he not able to do this by himself?

A Correct. He asked for assistance just with the testing and the organizing of data, and I -- you know, you'd have to ask Andy about his schedule, but I believe he requested my help just because he felt that it was more work than he could take on.

Q Is it also because Andy doesn't do particle count testing and that's what you do?

A No. We both do particle count testing.

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Andy is very proficient at particle count testing or evaluating data.

Q Were you asked to do an evaluation of bacteria counting as part of your testing?

A No.

Q Is that something you don't know how to do?

A Correct.

Q Is that something Andy does or does not know how to do?

A I don't know. You would have to ask Andy how he felt about that.

Q Did you or Andy suggest that bacteria counting should be done as part of your testing?

A We did not.

Q For the particle counter that you used, tell me why you chose that particular particle counter.

A It's a well-respected particle counter that we've used for years, and it's one of the probably leading brands on the market.

Q Had you used it before?

A For several years, yes.

Q You're familiar with how to use it?

A Yes.

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Q Let me go back to the question that you put in your report.

You said you were retained to evaluate whether the Bair Hugger "generates and/or omits particles."

Did you mean "omits" or "emits"?

A "Generates" meaning how the particles are either produced from the machine or through the machine.

Q Well, I'm just first starting with the word "omit."

Did you mean "emits" or "omits"?

MS. ZIMMERMAN: Emits.

THE WITNESS: Emits.

BY MS. LEWIS:

Q Emits. Okay.

And then what did you mean by "generates"?

A As part of the internal portions or the internal workings of the Bair Hugger; the blower, the -- the unit that drives the air, that forced the velocity of air through the hose, the other internal components of the Bair Hugger.

Q How did you learn about the workings of the Bair Hugger? Did you look at any document, owner's

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manual or something, or service manual?

A We were given a owner's manual, I think, in the box. There might have been one in the box, I believe. Yes.

Q Was there a service manual in there as well?

A I do not recall if there was a service manual. I believe there was, yes.

Q You've got some understanding of the Bair Hugger, the fact that there's the warming unit, there's the hose that the blanket attaches to; correct?

A Yes.

Q You understand that air goes into the warming unit, gets warmed up, and then goes out the hose into the blanket; correct?

A Correct.

Q That's what I'm now trying to understand, what you mean by it "generates" particles. You mean it actually creates them or just -- when you mean "generate," they come out of?

A Both. I think there's internal particles that could be generated as a result of the electrical components of the system. And there's also other

1 MICHAEL WAYNE BUCK  
 2 particles that could possibly come through the unit  
 3 into the hose.  
 4 Q Did you do testing on things that could  
 5 come -- that could be generated within the unit?  
 6 A That was why we put the probe inside the  
 7 hose to test what was coming from the unit itself.  
 8 Q I understand that's what you said earlier,  
 9 is that the particle counter looks at the number of  
 10 particles and the size of particles; correct?  
 11 A Correct.  
 12 Q The particle counter can't differentiate  
 13 what type of particles are coming out; correct?  
 14 A Correct.  
 15 Q So you didn't do any testing, did you, on  
 16 types of particles that are coming out; correct?  
 17 MS. ZIMMERMAN: Object to form. Misstates  
 18 the testimony.  
 19 THE WITNESS: Correct.  
 20 BY MS. LEWIS:  
 21 Q I understand from your report that you did  
 22 three type -- tests; right?  
 23 A Yes.  
 24 Q You mention that you had two Bair Hugger  
 25 warming units. And there was a little confusion in

1 MICHAEL WAYNE BUCK  
 2 your report, so let me ask you to clarify.  
 3 You said you had a model 750 and a model  
 4 775; right?  
 5 A Correct.  
 6 Q Where did you get those models from?  
 7 A The old one was the used one; it was  
 8 furnished to us by counsel. And the new one was  
 9 purchased from a -- the supplier -- a supplier.  
 10 Q The used one was the model 750?  
 11 A Yes.  
 12 Q And that's the one you got from counsel?  
 13 A Yes.  
 14 MS. ZIMMERMAN: And if I can clarify, both  
 15 of these devices were provided by counsel, a new one  
 16 and a used one, and the --  
 17 MS. LEWIS: Okay.  
 18 MS. ZIMMERMAN: -- new one was from you.  
 19 MS. LEWIS: Okay.  
 20 MS. ZIMMERMAN: Your folks.  
 21 MS. LEWIS: All right.  
 22 MS. ZIMMERMAN: I think that there is a typo  
 23 that we realized --  
 24 MS. LEWIS: Yeah.  
 25 MS. ZIMMERMAN: -- yesterday in the

1 MICHAEL WAYNE BUCK  
 2 footnote --  
 3 MS. LEWIS: Yeah.  
 4 MS. ZIMMERMAN: -- because it says --  
 5 MS. LEWIS: It says both devices are model  
 6 750, but --  
 7 MS. ZIMMERMAN: Right.  
 8 THE WITNESS: Yes. That's --  
 9 MS. LEWIS: Okay.  
 10 MS. ZIMMERMAN: Both devices were provided  
 11 by counsel. One's a 750. One's a 775.  
 12 MS. LEWIS: All right.  
 13 BY MS. LEWIS:  
 14 Q So there -- you tested a 750 --  
 15 A Yes.  
 16 Q -- model and a 775 model?  
 17 A Correct.  
 18 Q Both of those models came from counsel;  
 19 correct?  
 20 A Correct.  
 21 Q For the used model, what information did you  
 22 learn about how it had been used?  
 23 A Just that it had been used. I don't know  
 24 where it had been used or how it had been used.  
 25 There was a brief comment from counsel that it had

1 MICHAEL WAYNE BUCK  
 2 been used as a demonstration model.  
 3 Q Do you know any more about its use before  
 4 you got it?  
 5 A I do not.  
 6 Q Did you think that was important?  
 7 A No. I guess it was -- we were just testing  
 8 the unit so -- just looked at what we were asked to  
 9 test.  
 10 Q And the new one, because it was new, were  
 11 you informed that it had not been used before at  
 12 all?  
 13 A Correct.  
 14 Q Did you look at those filters before you  
 15 started your testing, take a physical look at them?  
 16 A Yes.  
 17 Q When you do particle counting generally --  
 18 A Uh-huh.  
 19 Q -- do you usually test -- for example, if  
 20 you're doing particle counting in the OR, do you do a  
 21 first test to see what the particle amounts are in a  
 22 room, and then do your testing so that you have  
 23 something to compare?  
 24 A We use control samples inside and outside of  
 25 the ORs to evaluate whether or not there is a

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Q All right. So you've got it connected. Now what do you do -- did you do? You've got the probe in, you've got the blanket in.

Who put the blanket in?

A Andy and I.

Q And you -- both of you or --

A Yes.

Q Why?

A I guess I was just helping. He was at one end, I was at the other. We were trying to fit it as best we could into the container.

Q It's a little squished?

A It was a little squished, yes.

Q Because there wasn't enough room in the container?

A Correct.

Q Was this a blanket that you opened up from its container from the plastic wrap?

A Yes.

Q So this was not a blanket that had been used before?

A No.

Q Okay. So you opened it up and got it in here as best you could; right?

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A Yes.

Q Did you wear any gloves or anything when you put it in?

A I don't believe so, no.

Q All right. So it's in. Now what did you do?

A We went through the testing process that we had laid out where we zeroed the particle counter --

Q Uh-huh.

A -- and then we took samples inside the room, plus the box.

Q Explain that. Where it says "background room, plus box," what --

A So --

Q -- does that mean?

A -- we took background samples inside the room, and then we took samples inside the box. The room -- we took samples inside the box in the room for background. Because, ultimately, what we wanted to know was when we turned the Bair Hugger on, what particles came out of the blanket.

Q And you can't sterilize the container; right?

A The container was wiped down with the same

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cloth or material cleaning agent that I used to wipe the carts down with in our initial experiments in the clean room.

Q You don't put that in your report that you wiped down the container?

A No. It would just be, I guess, something that we would do regularly as a means of doing work, this type of work.

Q What did you wipe down the container with?

A I believe it was a wipe. I'd have to check and see. It was a standard type of cleaner wipe that would be used in health care settings.

Q Was it a disinfectant or just a wipe?

A It was a disinfectant of some sort. I don't exactly know what the claims were on the side of the container. I could furnish you with that information if you would like.

Q Where did you get the disinfectant from?

A I believe it was from our storage -- not storage -- but our lab area where we have wipes where we clean countertops, those types of things.

Q Your lab in your -- your office?

A In our building, yes.

Q But you were in Precision Air, so I'm saying

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you --

A Took the wipes with us.

Q You brought the wipes with you?

A We had supplies, tape, wipes, utility knife, those types of things.

Q You agree that you did not sterilize the box, the container; right?

A I wiped it down. I did not sterilize it.

Q Because you can't sterilize; correct?

A I wiped it down with a -- disinfecting wipes. I did not sterilize it in terms of -- I don't -- I don't know exactly what you mean by "sterilize."

Q You didn't get rid of all the bacteria in the container; correct?

A No.

Q You can't say how much bacteria or even particles were in the container when you finished wiping it out?

A I cannot. We can only go by what the particle counter counted during our initial testing or during the phases of the testing before we turn the Bair Hugger on.

Q And so -- all right. And your putting in

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1 MICHAEL WAYNE BUCK  
 2 the blanket into the container, did that generate  
 3 particles?  
 4 A I don't know if it did or not.  
 5 Q Probably did?  
 6 A We could have put particles in the container  
 7 as we were putting the Bair Hugger in there -- or the  
 8 blanket in there. That's a possibility, yes.  
 9 Q Isn't it a probability?  
 10 A I -- there were particles in there when we  
 11 counted so that's a possibility, yes. It could be a  
 12 probability, yes.  
 13 Q It was probably [sic] that you added  
 14 particles?  
 15 A I can't say for sure, but it could be since  
 16 we are humans and we were wearing clothes and we were  
 17 manipulating a blanket.  
 18 Q According to your graph, you ran the test  
 19 for 24 minutes; is that about right?  
 20 A I believe so, yes.  
 21 Q Why 24 minutes?  
 22 A I think because we felt that that was an  
 23 adequate time to complete the testing that we wanted  
 24 to do, which was basically see if particles came out  
 25 of the blanket while the Bair Hugger was running.

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1 MICHAEL WAYNE BUCK  
 2 Q -- right?  
 3 Let's say, for -- for example, on the top of  
 4 page 16 of your report, which is the model 750, your  
 5 y-axis only goes to 14,000; correct?  
 6 A Correct.  
 7 Q Your other graphs you went -- for one of  
 8 them it went to 10 million; right?  
 9 A In previous tests?  
 10 Q Well, the old for the 750 outside clean  
 11 room, your logarithm is 10 million; right?  
 12 A I -- what page are you on?  
 13 Q On page 12.  
 14 A Oh, okay.  
 15 Q I hope I counted it right. I think so.  
 16 A One, two, three, four, five, six -- seven  
 17 zeros, yes.  
 18 Q So that logarithm is 10 million?  
 19 A Right.  
 20 Q The log at the bottom of page 12 where  
 21 you're also doing the outside clean room, you only  
 22 used a logarithm at the top on the y-axis of  
 23 1 million; right?  
 24 A Yes.  
 25 Q Why didn't you use the same logarithm for

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1 MICHAEL WAYNE BUCK  
 2 Q But since you did 44 and 46 minutes with  
 3 just the hose, why just 24 minutes with the  
 4 blanket?  
 5 A There weren't as many modes or as many  
 6 procedures that we wanted to test. We wanted to  
 7 basically test if particles came out of the blanket  
 8 when the Bair Hugger was running.  
 9 Q So you didn't care what temperature it was  
 10 like you did when you were just looking at particles  
 11 at the hose?  
 12 MS. ZIMMERMAN: Object --  
 13 THE WITNESS: I --  
 14 MS. ZIMMERMAN: -- to form. Misstates the  
 15 witness's testimony.  
 16 THE WITNESS: We basically felt like the  
 17 Bair Hugger was on and pushing particles out or it  
 18 was operating that we felt like we were testing what  
 19 was going to come out of the blanket.  
 20 BY MS. LEWIS:  
 21 Q You already had an idea?  
 22 A No, I did not.  
 23 Q This -- the two graphs for your testing on  
 24 the blanket has a different y-axis --  
 25 A Yes.

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1 MICHAEL WAYNE BUCK  
 2 both so that you could compare sort of apples to  
 3 apples?  
 4 A The numbers don't go past -- except for one  
 5 particular value on the top graph -- go past a  
 6 million; so, therefore, I think the other -- the  
 7 chart just automatically added another value above  
 8 that. But if you look, the values are all -- are the  
 9 same for both graphs on the y-axis.  
 10 Q On the y-axis --  
 11 A One --  
 12 Q -- I'm saying --  
 13 A -- 1; 10; 100; 1,000; 10,000 -- I mean --  
 14 Q Uh-huh. But you could have plotted your  
 15 lower graph on a 10 million logarithm graph so that  
 16 they would be the same -- so you could, again,  
 17 compare apples to apples.  
 18 A Right. That -- that could have been done,  
 19 yes. In fact, I -- I did not manipulate that that  
 20 way. That was just how the computer decided to do  
 21 that. I'm assuming because of this one value in the  
 22 middle, but --  
 23 Q Being above?  
 24 A Yes. I believe it added another segment to  
 25 the graph. I did not intentionally do that.

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1 MICHAEL WAYNE BUCK  
 2 BY MS. LEWIS:  
 3 Q So if we removed from your graph those size  
 4 particles where, again, based on the reference that  
 5 you've got to have a particle size of 4 microns to  
 6 contain bacteria, this chart would look quite  
 7 different; right?  
 8 MS. ZIMMERMAN: Object again to form.  
 9 Foundation. Misstating the witness's testimony  
 10 and misstating the reports and the data underlying  
 11 it. It also misstates prior testimony from the  
 12 witness.  
 13 BY MS. LEWIS:  
 14 Q You can go ahead and answer.  
 15 A According to what you said, the graph would  
 16 look different, yes.  
 17 Q Let me show you another graph I've done, and  
 18 you can tell me if it is -- if it accurately takes  
 19 out particles 2 microns and below.  
 20 MS. ZIMMERMAN: Is this being marked too?  
 21 9?  
 22 MS. LEWIS: That's 9.  
 23 (Exhibit 9 is marked for identification.)  
 24 MS. ZIMMERMAN: Just for the record, I'm  
 25 going to object again that Exhibit 9 is prepared by

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1 MICHAEL WAYNE BUCK  
 2 counsel, not by the witness. And so to the extent  
 3 the questions are being posed to the witness about  
 4 this that -- he hasn't prepared this document, and it  
 5 may or may not reflect the information provided in  
 6 his report.  
 7 MS. LEWIS: Yeah. I'll represent that I  
 8 prepared that.  
 9 BY MS. LEWIS:  
 10 Q So do you still understand the question?  
 11 A Yes, I do.  
 12 Q Okay.  
 13 A Yes. That would be what the graph would  
 14 look like if you take away the columns that you  
 15 mentioned.  
 16 Q Okay. And I have one more to show you. If  
 17 we again compare apples to apples like we did for  
 18 your second evaluation and we put them both on the  
 19 same linear scale.  
 20 A Okay.  
 21 Q Let me show you that graph that I also  
 22 prepared, and you can tell me if it's accurate.  
 23 (Exhibit 10 is marked for identification.)  
 24 MS. ZIMMERMAN: And, again, for the record,  
 25 I'll say that this Exhibit 10 was prepared by

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1 MICHAEL WAYNE BUCK  
 2 counsel, I think over lunch hour, and was not  
 3 prepared by the witness and may or may not reflect  
 4 the data that is in his report and the underlying  
 5 hard data that he's been testifying about this  
 6 morning.  
 7 BY MS. LEWIS:  
 8 Q Does that look about right -- accurate?  
 9 It's just again taking that --  
 10 A Oh.  
 11 Q -- upper one --  
 12 A Okay. So --  
 13 Q -- and putting --  
 14 A -- the same.  
 15 Q -- it on a --  
 16 A Right.  
 17 Q -- 30,000 --  
 18 A Yeah.  
 19 Q -- y-axis.  
 20 A Yes. Based on what you said, it looks  
 21 correct.  
 22 Q After you ran this for 24 minutes for both  
 23 the 750 and the 775, did you do anything else during  
 24 this third evaluation?  
 25 MS. ZIMMERMAN: Object to form.

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1 MICHAEL WAYNE BUCK  
 2 BY MS. LEWIS:  
 3 Q With respect to your testing, did you do any  
 4 further -- was there any other part of the test in  
 5 the third evaluation that we haven't discussed?  
 6 A No.  
 7 Q You turned it off. Was there anything else  
 8 that you did during this third evaluation?  
 9 A No.  
 10 Q Was this third evaluation conducted in close  
 11 proximity to a surgical site?  
 12 A It would be -- simulated operating room  
 13 table. But an actual surgical site, no, it was --  
 14 there was no person there.  
 15 Q Did you conduct this third evaluation with  
 16 the use of an anesthesia drape?  
 17 A No.  
 18 Q Did you do any testing to qualify the  
 19 types -- or categorize the types of particles that  
 20 were coming out, other than size?  
 21 A No.  
 22 Q I want to talk about the conclusions that  
 23 you reached on page 17. When we were looking at  
 24 Exhibit 6, I believe you testified that you weren't  
 25 relying on any articles or documents listed in

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1 MICHAEL WAYNE BUCK  
 2 Exhibit 6; is that right?  
 3 A That's correct.  
 4 Q Your statement in your conclusion --  
 5 conclusion section on page 17 of your report says,  
 6 first sentence:  
 7 "The evaluations showed clearly the  
 8 Bair Huggers, through all operational modes,  
 9 demonstrated increased production of  
 10 particles from internal and/or external  
 11 sources."  
 12 What do you mean -- "increased"? Compared  
 13 to what?  
 14 A Increase basically -- when the machine was  
 15 on, it was producing particles either internally or  
 16 through the unit that we measured using the particle  
 17 counter.  
 18 Q But how is it increased? What did you  
 19 compare it to to say it's now increased?  
 20 A I guess the increase would be from the time  
 21 that we started sampling or the periods of sampling  
 22 to the time that we finished sampling that there was  
 23 an increase in the particles at certain times.  
 24 Q Is that what you meant? That during your  
 25 test you saw an increase? Is that what you're

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1 MICHAEL WAYNE BUCK  
 2 saying?  
 3 A Particles were produced as a result of  
 4 running the machine -- or particles were measured as  
 5 a result of running the machine.  
 6 Q Well, I understand you were measuring  
 7 particles. I'm trying to understand how you can  
 8 conclude that your testing showed increased  
 9 production of particles.  
 10 How did you show an increase in particles?  
 11 Because "increase" means it's -- you're comparing it  
 12 to some baseline. So what are you comparing it to to  
 13 say there was an increased production?  
 14 A Well, when we were in the clean room, we  
 15 started basically at that low level and particles  
 16 were increased as we ran the machine. And we also  
 17 started from a zero point from zeroing the machine,  
 18 for the particle counter, so particles were increased  
 19 as the machine was running.  
 20 Q As the machine was running, the warming unit  
 21 is taking in air and particles; right?  
 22 A Correct.  
 23 Q So how did you reach a conclusion that there  
 24 was an increase? Because you didn't measure the  
 25 number of particles going in; correct?

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1 MICHAEL WAYNE BUCK  
 2 MS. ZIMMERMAN: Object to form.  
 3 THE WITNESS: I'm sorry. We didn't measure  
 4 the what?  
 5 BY MS. LEWIS:  
 6 Q You told me you did not measure the number  
 7 of particles going into the warming unit; correct?  
 8 A Yes. That's correct.  
 9 Q So how did you reach a conclusion that they  
 10 increased when you haven't taken into account the  
 11 number of particles that went in?  
 12 A The particles that we measured were only in  
 13 the flex tube of the Bair Hugger, and those particles  
 14 were counted; so, therefore, we were -- the number  
 15 was increased -- or that number increased as we  
 16 counted or as we were running our experiments.  
 17 Q But do you understand that the bottom of the  
 18 warming unit is taking in air, which means it's  
 19 taking in particles; right?  
 20 MS. ZIMMERMAN: Object to form.  
 21 THE WITNESS: Yes.  
 22 BY MS. LEWIS:  
 23 Q And there was no way you made a distinction  
 24 as to what particles were going in compared to the  
 25 particles going out; correct?

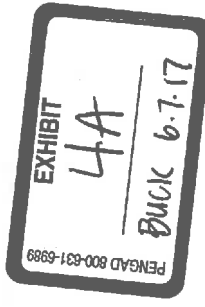
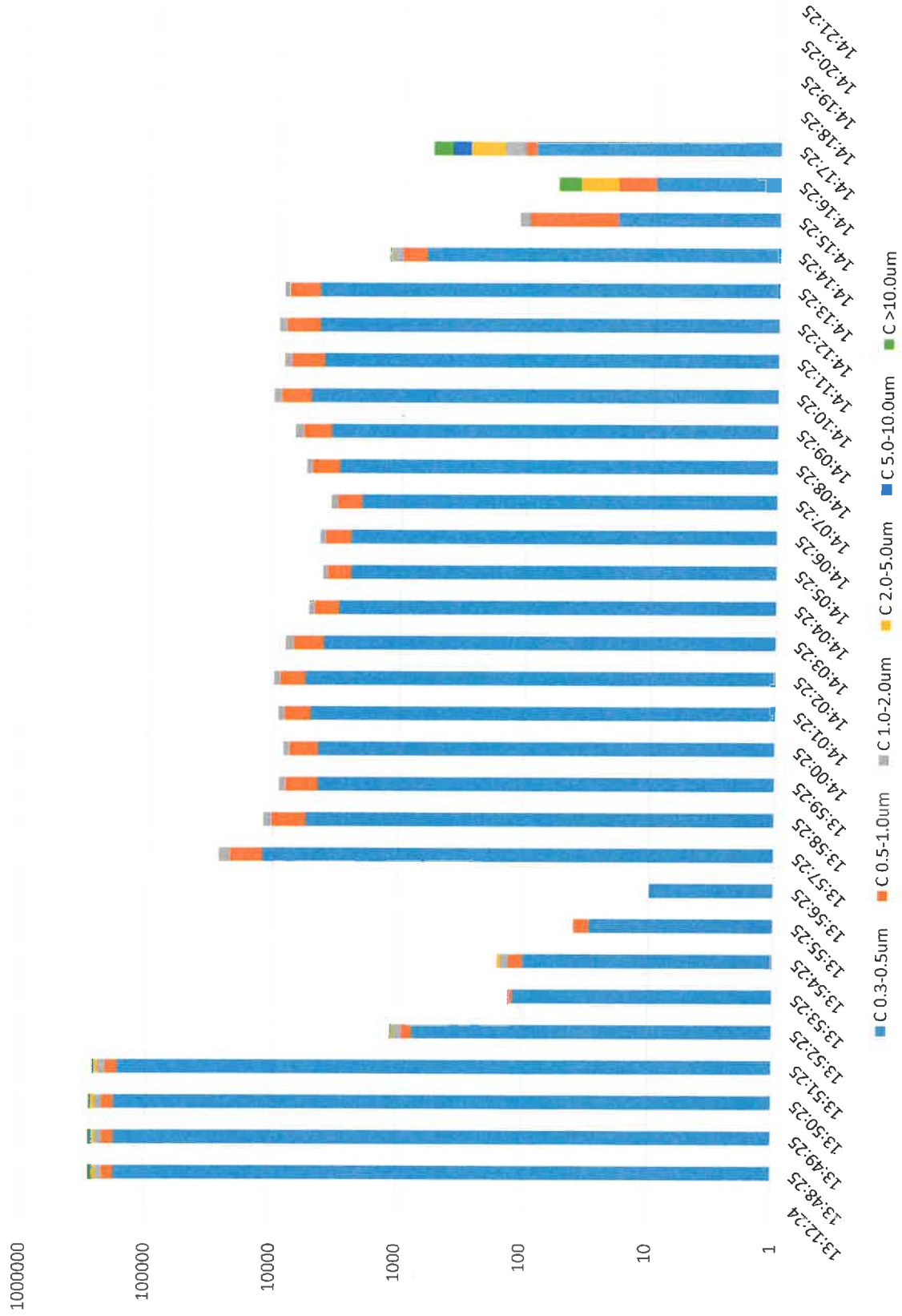
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1 MICHAEL WAYNE BUCK  
 2 MS. ZIMMERMAN: Object, again, to form.  
 3 THE WITNESS: I guess the way you're asking  
 4 the question, that would be correct.  
 5 BY MS. LEWIS:  
 6 Q Is there any other reason why you're saying  
 7 your testing showed an increased production of  
 8 particles?  
 9 A Because that's what we felt that we  
 10 measured, was an increase in particles as a result of  
 11 the steps that we put the Bair Hugger through.  
 12 Q But you now understand that there was air  
 13 coming into the warming unit that had particles in  
 14 it?  
 15 MS. ZIMMERMAN: Object to the form of the  
 16 question --  
 17 MS. LEWIS: Right?  
 18 MS. ZIMMERMAN: -- foundation. And  
 19 misstates the witness's testimony.  
 20 THE WITNESS: That air was filtered, run  
 21 through a filter too.  
 22 BY MS. LEWIS:  
 23 Q Correct.  
 24 A Right.  
 25 Q And did you take into account the particles

# **EXHIBIT DX50**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS

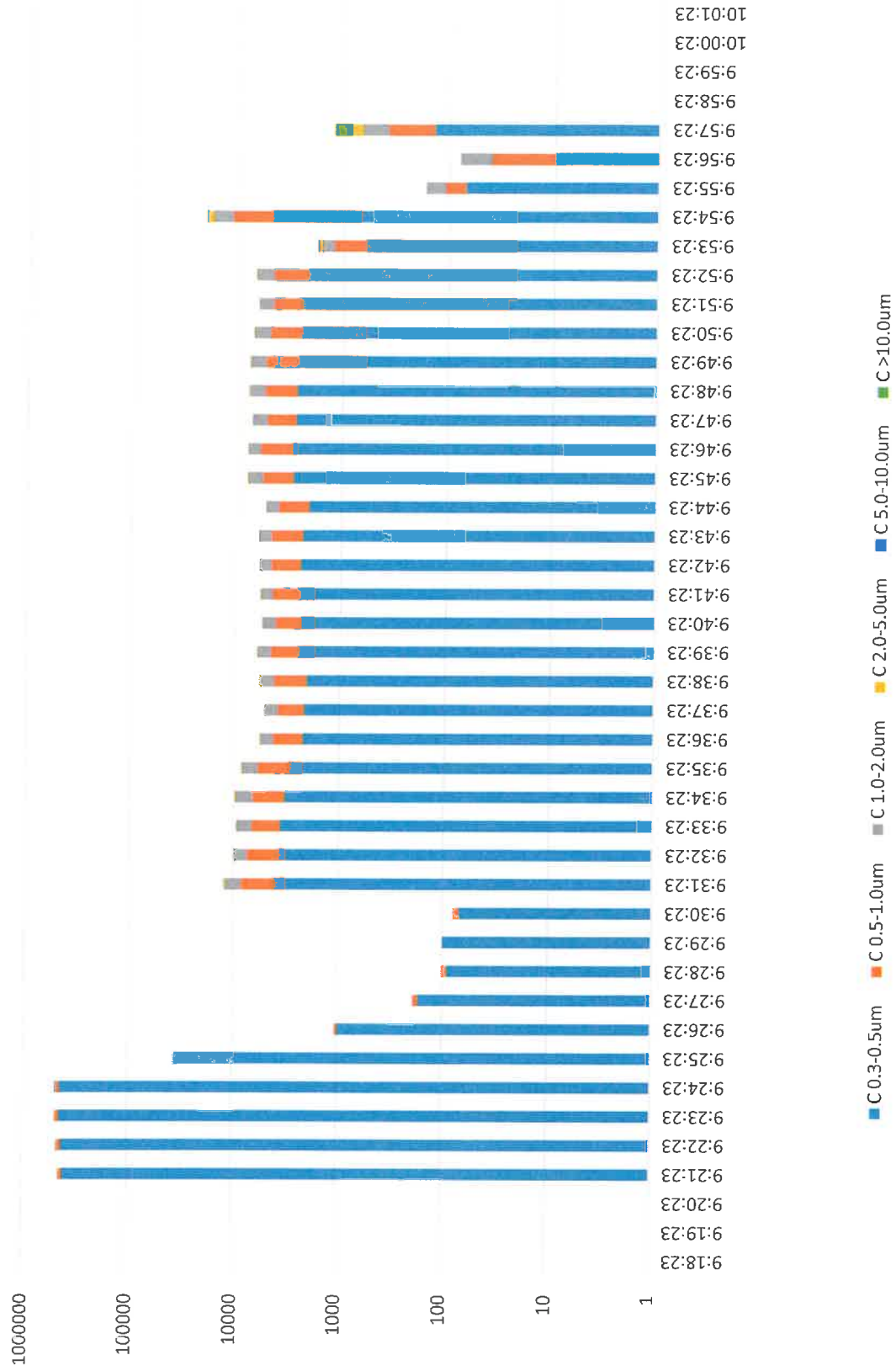
# Old Bair Hugger 12\_14\_16 Inside Clean Room



LocationNum	Date	Time	C 0.3- 0.5um	C 0.5- 1.0um	C 1.0- 2.0um	C 2.0- 5.0um	C 5.0- 10.0um	C >10.0um	Temperature F
Zero Particle Counter 1	12/14/2016	13:12:24	0	0	0	0	0	0	71.65
Background 2	12/14/2016	13:48:25	179171	43795	30354	15752	7851	4461	66.76
Background 3	12/14/2016	13:49:25	178980	45038	31035	15513	7841	4631	65.91
Background 4	12/14/2016	13:50:25	179190	44777	31945	16663	7981	4561	65.77
Background 5	12/14/2016	13:51:25	169718	42467	29635	16223	7671	4101	65.61
Clean Room ON 6	12/14/2016	13:52:25	760	170	150	30	10	10	64.74
Clean Room ON 7	12/14/2016	13:53:25	120	10	0	0	0	0	65.3
Clean Room ON 8	12/14/2016	13:54:25	100	30	20	10	0	0	66.34
Clean Room ON 9	12/14/2016	13:55:25	30	10	0	0	0	0	66.99
Clean Room ON 10	12/14/2016	13:56:25	10	0	0	0	0	0	67.69
Ambient Bair Hugger11	12/14/2016	13:57:25	12182	9892	4141	460	110	40	68.32
Ambient Bair Hugger12	12/14/2016	13:58:25	5541	4901	1520	80	0	20	69.35
Ambient Bair Hugger13	12/14/2016	13:59:25	4481	3621	910	30	0	10	69.71
Ambient Bair Hugger14	12/14/2016	14:00:25	4471	3121	770	20	0	10	69.93
Ambient Bair Hugger15	12/14/2016	14:01:25	5181	3201	870	0	10	0	81.7
Bair Hugger 38° 16	12/14/2016	14:02:25	5721	3361	970	20	0	0	84.34
Bair Hugger 38° 17	12/14/2016	14:03:25	4131	3081	1010	50	0	0	85.64
Bair Hugger 38° 18	12/14/2016	14:04:25	3141	1780	440	40	0	10	86.23
Bair Hugger 38° 19	12/14/2016	14:05:25	2540	1340	320	10	0	0	87.4
Bair Hugger 38° 20	12/14/2016	14:06:25	2550	1510	400	0	10	0	92.34
Bair Hugger 43° 21	12/14/2016	14:07:25	2100	1190	370	20	0	0	94.23
Bair Hugger 43° 22	12/14/2016	14:08:25	3171	2070	480	10	10	0	94.86
Bair Hugger 43° 23	12/14/2016	14:09:25	3711	2490	960	10	0	10	95.29
Bair Hugger 43° 24	12/14/2016	14:10:25	5401	3941	1260	40	20	30	96.01
Bair Hugger 43° 25	12/14/2016	14:11:25	4251	3561	940	100	10	10	96.15
Bair Hugger On-Side 26	12/14/2016	14:12:25	4641	3981	1030	70	10	0	96.75
Bair Hugger On-Side 27	12/14/2016	14:13:25	4671	3491	660	40	0	0	96.15
Bair Hugger On-Side 28	12/14/2016	14:14:25	660	380	210	20	10	20	76.21
Bair Hugger On-Side 29	12/14/2016	14:15:25	20	80	20	0	0	0	73.17
Bair Hugger On-Side 30	12/14/2016	14:16:25	10	10	0	20	0	20	71.91

BH Off Cln Rm ON	31	12/14/2016	14:17:25	90	20	50	140	120	180	68.14
BH Off Cln Rm ON	32	12/14/2016	14:18:25	0	0	0	0	0	0	66.24
BH Off Cln Rm ON	33	12/14/2016	14:19:25	0	0	0	0	0	0	65.03
BH Off Cln Rm ON	34	12/14/2016	14:20:25	0	0	0	0	0	0	64.35
BH Off Cln Rm ON	35	12/14/2016	14:21:25	0	0	0	0	0	0	63.61

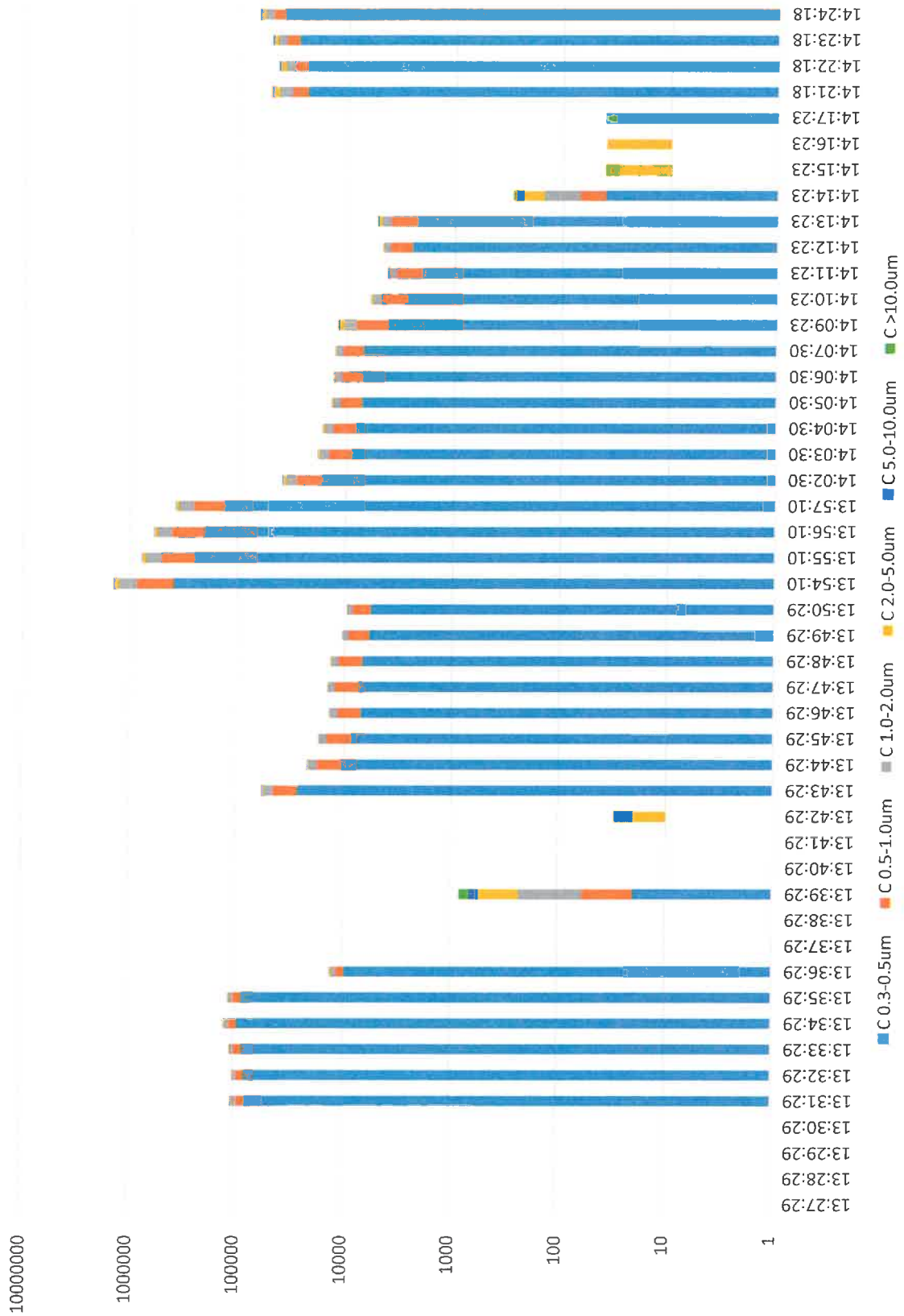
# New Bair Hugger 12\_28-16 Inside Clean Room



LocationNum	Date	Time	C 0.3- 0.5um	C 0.5- 1.0um	C 1.0- 2.0um	C 2.0- 5.0um	C 5.0- 10.0um	C >10.0um	Temperat ure F
Zero Particle Counter	12/28/2016	9:18:23		0	0	0	0	0	68.43
Zero Particle Counter	12/28/2016	9:19:23		0	0	0	0	0	67.06
Zero Particle Counter	12/28/2016	9:20:23		0	0	0	0	0	66.4
Background	12/28/2016	9:21:23	409564	32783	5960	1930	670	830	65.66
Background	12/28/2016	9:22:23	424881	35076	6361	1840	620	180	64.92
Background	12/28/2016	9:23:23	443144	36346	6341	1950	650	170	64.51
Background	12/28/2016	9:24:23	440213	34536	6811	2190	690	160	64.35
Clean Room ON	12/28/2016	9:25:23	33097	2470	490	170	40	20	64.06
Clean Room ON	12/28/2016	9:26:23	1000	50	0	10	0	0	64
Clean Room ON	12/28/2016	9:27:23	170	20	0	0	0	0	63.97
Clean Room ON	12/28/2016	9:28:23	90	10	0	0	0	0	64
Clean Room ON	12/28/2016	9:29:23	100	0	0	0	0	0	64.13
Clean Room ON	12/28/2016	9:30:23	70	10	0	0	0	0	64.08
Ambient Bair Hugger ON	12/28/2016	9:31:23	4081	4431	3441	370	90	60	65.84
Ambient Bair Hugger ON	12/28/2016	9:32:23	3681	3791	2490	250	0	0	66.16
Ambient Bair Hugger ON	12/28/2016	9:33:23	3601	3201	2570	150	10	0	66.51
Ambient Bair Hugger ON	12/28/2016	9:34:23	3271	3431	2991	370	0	0	66.76
Ambient Bair Hugger ON	12/28/2016	9:35:23	3031	2971	2470	170	30	20	66.99
Bair Hugger 38°	12/28/2016	9:36:23	2230	2070	1420	140	0	0	67.33
Bair Hugger 38°	12/28/2016	9:37:23	2180	1730	1330	70	0	0	67.46
Bair Hugger 38°	12/28/2016	9:38:23	2060	2250	1370	140	20	20	68.77
Bair Hugger 38°	12/28/2016	9:39:23	2480	2160	1510	120	0	10	70.9
Bair Hugger 38°	12/28/2016	9:40:23	2380	1750	1390	70	10	0	72.59
Bair Hugger 43°	12/28/2016	9:41:23	2440	2070	1240	170	0	0	73.49
Bair Hugger 43°	12/28/2016	9:42:23	2411	2250	1270	100	0	0	74.12
Bair Hugger 43°	12/28/2016	9:43:23	2310	2330	1380	120	0	0	74.61
Bair Hugger 43°	12/28/2016	9:44:23	2030	1950	1250	90	0	0	75.47
Bair Hugger 43°	12/28/2016	9:45:23	2891	2791	2150	180	0	0	76.03
Bair Hugger On-Side	12/28/2016	9:46:23	3001	3001	1820	170	0	0	76.59
Bair Hugger On-Side	12/28/2016	9:47:23	2741	2490	1930	160	0	0	76.84

Bair Hugger On-Side	12/28/2016	9:48:23	2700	2791	2180	190	10	0	77.07
Bair Hugger On-Side	12/28/2016	9:49:23	2660	2761	2130	200	10	0	77.16
Bair Hugger On-Side	12/28/2016	9:50:23	2450	2470	2100	150	0	10	77.36
Bair Hugger On-Side	12/28/2016	9:51:23	2470	2170	1670	120	0	0	77.45
Bair Hugger On-Side	12/28/2016	9:52:23	2160	2460	2110	170	0	0	77.63
BH Off Cln Rm ON	12/28/2016	9:53:23	610	630	360	120	20	10	76.64
BH Off Cln Rm ON	12/28/2016	9:54:23	4811	6781	5891	2060	570	260	75.49
BH Off Cln Rm ON	12/28/2016	9:55:23	70	40	60	0	0	0	74.14
BH Off Cln Rm ON	12/28/2016	9:56:23	10	30	40	0	0	0	73.06
BH Off Cln Rm ON	12/28/2016	9:57:23	140	250	290	180	120	260	73.96
Zero Particle Counter	12/28/2016	9:58:23	0	0	0	0	0	0	72.18
Zero Particle Counter	12/28/2016	9:59:23	0	0	0	0	0	0	70.72
Zero Particle Counter	12/28/2016	10:00:23	0	0	0	0	0	0	69.98
Zero Particle Counter	12/28/2016	10:01:23	0	0	0	0	0	0	69.85

Old Bair Hugger 12\_20\_16 Outside Clean Room Filter In/Filter Out



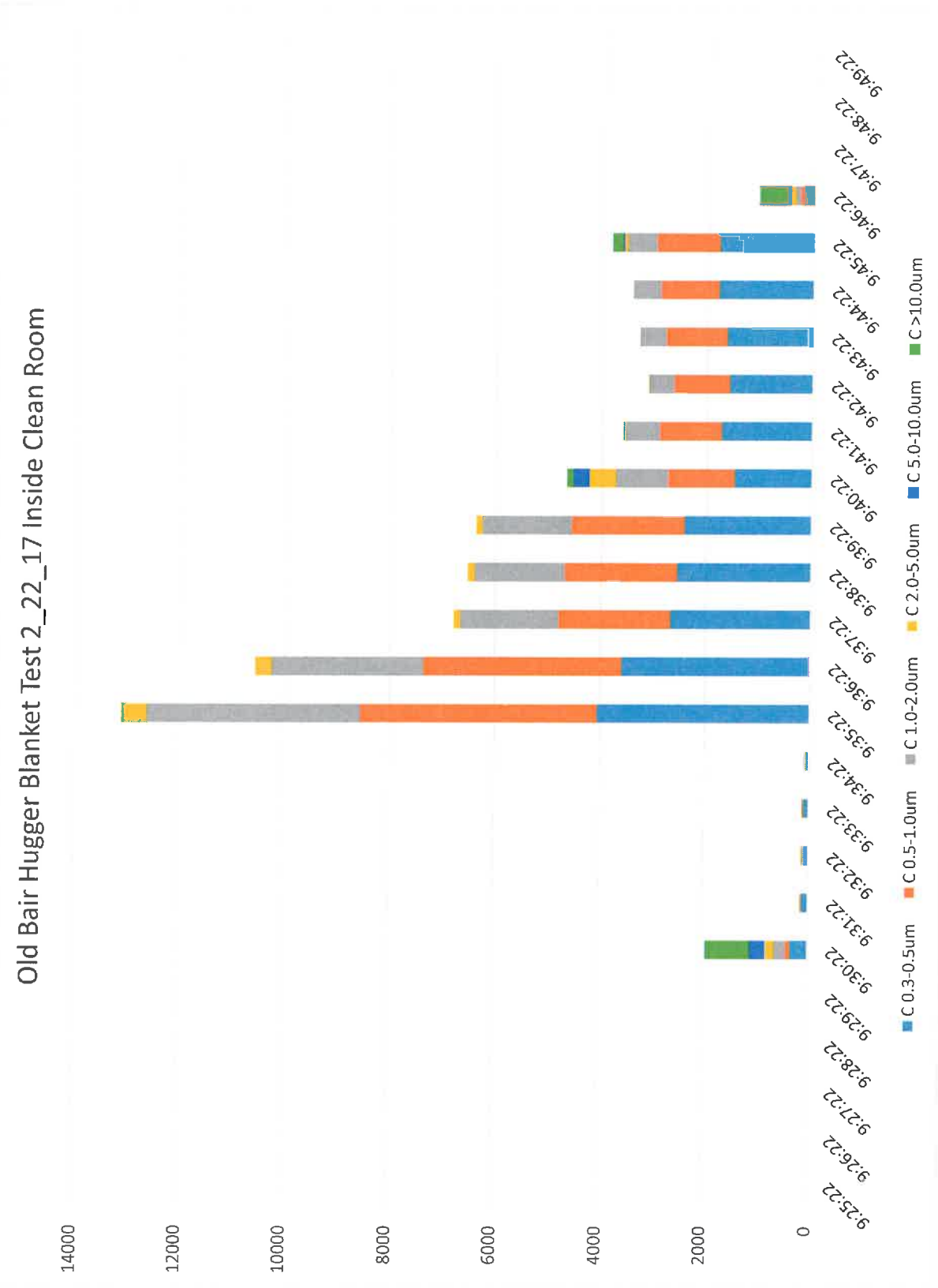
LocationNum	Date	Time	C 0.3-0.5um	C 0.5-1.0um	C 1.0-2.0um	C 2.0-5.0um	C 5.0-10.0um	C >10.0um	Temperature F
Zero Particle Counter	12/20/2016	13:27:29	0	0	0	0	0	10	66.7
Zero Particle Counter	12/20/2016	13:28:29	0	0	0	0	0	0	65.79
Zero Particle Counter	12/20/2016	13:29:29	0	0	0	0	0	0	65.28
Zero Particle Counter	12/20/2016	13:30:29	0	0	0	0	0	0	65.01
Background	12/20/2016	13:31:29	79547	15907	6723	2311	820	910	64.76
Background	12/20/2016	13:32:29	80905	14939	6470	1700	280	60	63.66
Background	12/20/2016	13:33:29	84954	16463	7651	2150	350	50	63.09
Background	12/20/2016	13:34:29	94426	19023	8501	3041	540	120	62.58
Background	12/20/2016	13:35:29	86844	17343	8011	2510	510	130	62.29
Background	12/20/2016	13:36:29	9662	1910	1110	400	90	40	62.96
Clean Room ON	12/20/2016	13:37:29	0	0	0	0	0	0	63.64
Clean Room ON	12/20/2016	13:38:29	0	10	0	0	0	0	64.09
Clean Room ON	12/20/2016	13:39:29	20	40	170	310	120	170	64.2
Clean Room ON	12/20/2016	13:40:29	0	0	0	0	0	10	64.33
Clean Room ON	12/20/2016	13:41:29	0	0	0	0	0	0	64.33
Ambient Bair Hugger	12/20/2016	13:42:29	0	0	10	10	10	0	64.53
Ambient Bair Hugger	12/20/2016	13:43:29	27175	18773	8811	1830	420	170	65.59
Ambient Bair Hugger	12/20/2016	13:44:29	10752	7021	3571	480	100	10	65.82
Ambient Bair Hugger	12/20/2016	13:45:29	8721	5791	2350	230	40	10	66.07
Ambient Bair Hugger	12/20/2016	13:46:29	7011	4441	2160	130	10	0	66.29
Bair Hugger 38°	12/20/2016	13:47:29	7521	4701	1950	180	0	10	66.52
Bair Hugger 38°	12/20/2016	13:48:29	6791	4581	1880	260	30	10	69.22
Bair Hugger 38°	12/20/2016	13:49:29	5921	3301	1190	160	10	0	71.92
Bair Hugger 38°	12/20/2016	13:50:29	5751	2751	970	110	40	10	73.31
Bair Hugger Filter Out	12/20/2016	13:54:10	385105	474925	394506	108053	20952	3500	73.42
Bair Hugger Filter Out	12/20/2016	13:55:10	243297	260639	200880	50148	7591	1100	75.22
Bair Hugger Filter Out	12/20/2016	13:56:10	203551	201040	144492	34795	5301	650	76.06
Bair Hugger Filter Out	12/20/2016	13:57:10	129459	127399	90464	21263	3361	520	76.73
Bair Hugger Filter IN	12/20/2016	14:02:30	16682	12162	7111	2090	510	250	74.62
Bair Hugger Filter IN	12/20/2016	14:03:30	9041	5501	3030	670	60	10	76.6
Bair Hugger Filter IN	12/20/2016	14:04:30	8341	4941	2630	630	110	100	77.56

Bair Hugger Filter IN	12/20/2016	14:05:30	7151	4241	1990	450	80	0	77.92
Bair Hugger Filter IN	12/20/2016	14:06:30	7141	3941	1730	380	50	20	77.95
Bair Hugger Filter IN	12/20/2016	14:07:30	6921	3991	1660	360	70	0	78.08
Bair Hugger In Clean Room	12/20/2016	14:09:23	4152	4062	2501	930	360	170	76.3
Bair Hugger In Clean Room	12/20/2016	14:10:23	2740	2000	1060	200	50	20	76.44
Bair Hugger In Clean Room	12/20/2016	14:11:23	2020	1480	460	120	40	40	76.46
Bair Hugger In Clean Room	12/20/2016	14:12:23	2480	1530	580	120	30	0	76.33
Bair Hugger In Clean Room	12/20/2016	14:13:23	2240	1740	830	290	140	10	76.41
BH Off Cln Rm ON	12/20/2016	14:14:23	40	30	80	80	40	20	73.74
BH Off Cln Rm ON	12/20/2016	14:15:23	0	0	10	20	0	10	71.82
BH Off Cln Rm ON	12/20/2016	14:16:23	0	0	10	30	0	0	70.39
BH Off Cln Rm ON	12/20/2016	14:17:23	20	0	0	0	10	10	69.62
Outside Control	12/20/2016	14:21:18	23957	10019	9809	5659	1640	370	67.08
Outside Control	12/20/2016	14:22:18	23474	8481	6951	4121	1430	260	65.35
Outside Control	12/20/2016	14:23:18	28834	9391	7311	3951	1510	250	64.11
Outside Control	12/20/2016	14:24:18	38805	11972	9521	4921	1420	300	63.43



LocationNum	Date	Time	C 0.3- 0.5um	C 0.5- 1.0um	C 1.0- 2.0um	C 2.0- 5.0um	C 5.0- 10.0um	C >10.0um	Temperature F
Zero Particle Counter	1/2/2017	8:44:45	0	0	0	0	0	0	69.91
Zero Particle Counter	1/2/2017	8:45:45	0	0	0	0	0	0	68.77
Zero Particle Counter	1/2/2017	8:46:45	0	0	0	0	0	0	68.11
Zero Particle Counter	1/2/2017	8:47:45	0	0	0	0	0	0	67.46
Background-Flex Tube	1/2/2017	8:48:45	618962	54535	36314	18492	11721	18132	66.65
Background-Flex Tube	1/2/2017	8:49:45	671163	46258	15623	5721	670	100	65.64
Background-Flex Tube	1/2/2017	8:50:45	678384	49149	18403	6491	950	110	64.96
Background-Flex Tube	1/2/2017	8:51:45	667622	49519	18673	6641	950	150	64.58
Background-Flex Tube	1/2/2017	8:52:45	668624	49000	18314	6181	790	50	64.15
Background-Flex Tube	1/2/2017	8:53:45	654161	50450	24155	11262	2480	2230	64.04
Clean Room ON	1/2/2017	8:54:45	59041	8352	7941	4781	1500	1170	63.88
Clean Room ON	1/2/2017	8:55:45	1600	2330	3331	2330	690	440	63.9
Clean Room ON	1/2/2017	8:56:45	290	440	980	810	180	140	64.02
Clean Room ON	1/2/2017	8:57:45	580	1170	1890	1190	270	380	64.17
Clean Room ON	1/2/2017	8:58:45	180	440	650	390	120	110	64.2
Clean Room ON	1/2/2017	8:59:45	320	520	600	330	80	20	64.38
Clean Room ON	1/2/2017	9:00:45	10	20	0	0	20	0	64.54
Ambient Bair Hugger	1/2/2017	9:08:52	18228	3890	3540	1740	630	510	69.76
Ambient Bair Hugger	1/2/2017	9:09:52	16172	3110	2170	840	360	250	69.42
Ambient Bair Hugger	1/2/2017	9:10:52	17423	3561	3721	1530	630	380	69.44
Ambient Bair Hugger	1/2/2017	9:11:52	15562	2990	2640	990	330	200	69.98
Ambient Bair Hugger	1/2/2017	9:12:52	14692	2790	1610	360	130	150	70.41
Bair Hugger Filter Out	1/2/2017	9:17:02	141477	132405	117274	36544	7821	4781	72.1
Bair Hugger Filter Out	1/2/2017	9:18:02	60219	25414	21493	7381	1350	600	72.09
Bair Hugger Filter Out	1/2/2017	9:19:02	62100	23154	19893	6721	1610	480	72.27
Bair Hugger Filter Out	1/2/2017	9:20:02	52749	13962	10702	3091	790	290	72.48
Bair Hugger Filter Out	1/2/2017	9:21:02	52558	16502	14042	4021	850	420	72.63
Bair Hugger Filter IN	1/2/2017	9:23:59	18165	4149	2679	510	90	50	73.81
Bair Hugger Filter IN	1/2/2017	9:24:59	15822	3330	2550	180	50	50	74.19
Bair Hugger Filter IN	1/2/2017	9:25:59	14612	3411	2450	330	40	30	74.84

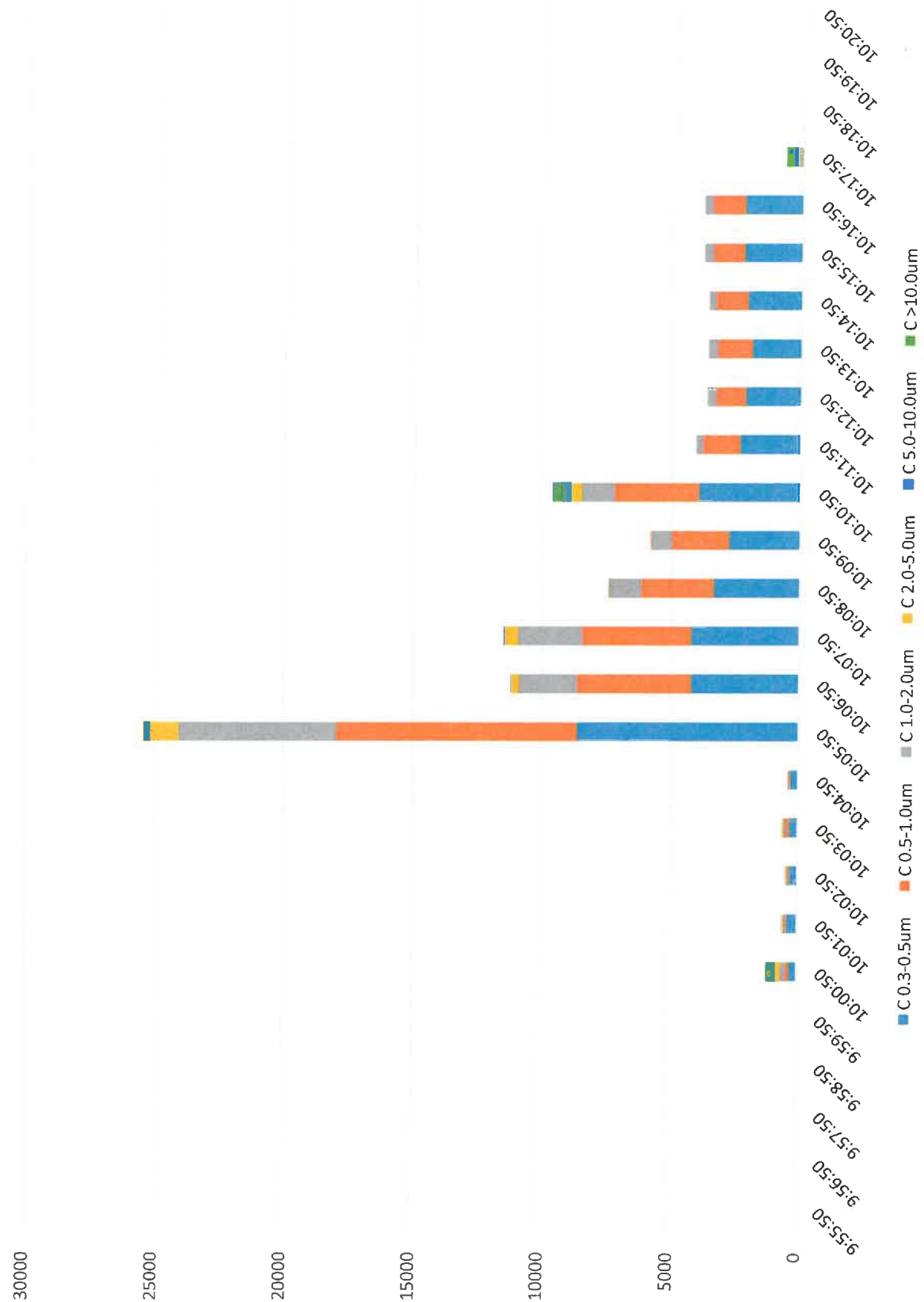
Bair Hugger Filter IN	1/2/2017	9:26:59	17413	3531	2550	130	0	0	73.18
Bair Hugger Filter IN	1/2/2017	9:27:59	16303	3541	2610	220	10	0	73.35
Bair Hugger Filter IN	1/2/2017	9:28:59	15882	3240	2000	130	10	0	73.36
Bair Hugger In Clean Room	1/2/2017	9:30:25	2911	3272	2691	150	0	0	73.42
Bair Hugger In Clean Room	1/2/2017	9:31:25	2680	3060	2200	190	0	0	73.36
Bair Hugger In Clean Room	1/2/2017	9:32:25	2430	2750	2450	110	0	0	73.36
Bair Hugger In Clean Room	1/2/2017	9:33:25	2750	3250	2420	390	40	0	73.31
Bair Hugger In Clean Room	1/2/2017	9:34:25	270	500	590	540	190	150	70.74
BH Off Cln Rm ON	1/2/2017	9:35:25	0	20	0	0	0	20	69.08
BH Off Cln Rm ON	1/2/2017	9:36:25	0	0	0	0	0	0	67.8
BH Off Cln Rm ON	1/2/2017	9:37:25	0	0	0	0	0	0	66.67
Outside Control	1/2/2017	9:38:25	323589	18133	2880	920	200	140	67.03
Outside Control	1/2/2017	9:39:25	644217	36666	2920	410	150	10	65.68
Outside Control	1/2/2017	9:40:25	728829	39846	3401	600	170	30	64.9
Outside Control	1/2/2017	9:41:25	783478	44147	3280	360	80	30	64.22



Location	Date	Time	C 0.3- 0.5um	C 0.5- 1.0um	C 1.0- 2.0um	C 2.0- 5.0um	C 5.0- 10.0um	C >10.0um	Temperature F
Zero Particle Counter	2/22/2017	9:25:22	0	0	0	0	0	0	66.81
Zero Particle Counter	2/22/2017	9:26:22	0	0	0	0	0	0	66.51
Zero Particle Counter	2/22/2017	9:27:22	0	0	0	0	0	0	66.42
Zero Particle Counter	2/22/2017	9:28:22	0	0	0	0	0	0	66.34
Zero Particle Counter	2/22/2017	9:29:22	0	0	0	0	0	0	66.69
Background Room + Box	2/22/2017	9:30:22	330	100	210	160	310	840	67.19
Background Room + Box	2/22/2017	9:31:22	130	10	10	20	0	0	66.7
Background Room + Box	2/22/2017	9:32:22	100	10	20	30	0	0	66.54
Background Room + Box	2/22/2017	9:33:22	110	20	0	20	0	0	66.45
Background Room + Box	2/22/2017	9:34:22	70	0	0	20	10	0	66.45
Bair Hugger Inside Box 43°	2/22/2017	9:35:22	4051	4511	4041	430	20	30	66.85
Bair Hugger Inside Box 43°	2/22/2017	9:36:22	3591	3771	2871	320	0	0	67.96
Bair Hugger Inside Box 43°	2/22/2017	9:37:22	2671	2130	1860	130	0	0	69.46
Bair Hugger Inside Box 43°	2/22/2017	9:38:22	2541	2150	1700	140	0	0	70.56
Bair Hugger Inside Box 43°	2/22/2017	9:39:22	2410	2160	1680	120	0	0	71.47
Bair Hugger Blanket In Box	2/22/2017	9:40:22	1470	1270	990	500	310	120	72.59
Bair Hugger Blanket In Box	2/22/2017	9:41:22	1720	1190	640	20	20	10	73.98
Bair Hugger Blanket In Box	2/22/2017	9:42:22	1570	1070	470	20	0	0	74.88
Bair Hugger Blanket In Box	2/22/2017	9:43:22	1630	1170	490	10	0	0	75.2
Bair Hugger Blanket In Box	2/22/2017	9:44:22	1790	1120	520	10	0	0	75.65
Bair Hugger Blanket In Box	2/22/2017	9:45:22	1780	1210	550	60	40	200	75.18

Zero Particle Counter	2/22/2017	9:46:22	200	80	80	90	80	520	71.2
Zero Particle Counter	2/22/2017	9:47:22	0	0	0	0	0	0	70.41
Zero Particle Counter	2/22/2017	9:48:22	0	0	0	0	0	0	69.66
Zero Particle Counter	2/22/2017	9:49:22	0	0	0	0	0	0	69.08

New Bair Hugger Blanket Test 2\_22\_17 Inside Clean Room



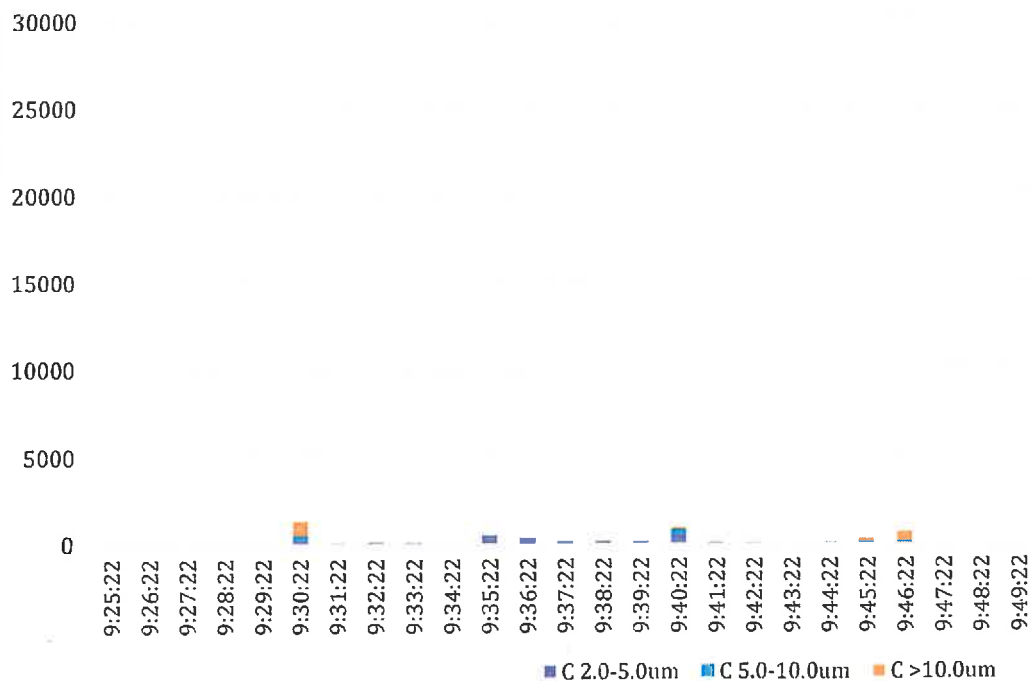
Location	Date	Time	C 0.3- 0.5um	C 0.5- 1.0um	C 1.0- 2.0um	C 2.0- 5.0um	C 5.0- 10.0um	C >10.0um	Temperature F
Zero Particle Counter	2/22/2017	9:55:50	0	0	0	0	0	0	69.26
Zero Particle Counter	2/22/2017	9:56:50	0	0	0	0	0	0	68.65
Zero Particle Counter	2/22/2017	9:57:50	0	0	0	0	0	0	68.29
Zero Particle Counter	2/22/2017	9:58:50	0	0	0	0	0	0	67.95
Zero Particle Counter	2/22/2017	9:59:50	0	0	0	0	0	0	67.66
Bair Hugger Room + Box	2/22/2017	10:00:50	320	150	190	170	150	200	66.96
Bair Hugger Room + Box	2/22/2017	10:01:50	410	60	60	50	10	10	66.69
Bair Hugger Room + Box	2/22/2017	10:02:50	300	50	70	60	10	0	66.61
Bair Hugger Room + Box	2/22/2017	10:03:50	340	140	80	60	0	10	66.58
Bair Hugger Room + Box	2/22/2017	10:04:50	300	60	40	30	0	0	66.49
Bair Hugger Inside Box 43°	2/22/2017	10:05:50	8591	9381	6101	1100	190	70	67.73
Bair Hugger Inside Box 43°	2/22/2017	10:06:50	4201	4431	2250	300	20	10	69.55
Bair Hugger Inside Box 43°	2/22/2017	10:07:50	4221	4211	2500	490	50	20	71.2
Bair Hugger Inside Box 43°	2/22/2017	10:08:50	3361	2820	1220	40	0	10	72.3
Bair Hugger Inside Box 43°	2/22/2017	10:09:50	2780	2230	780	60	10	0	73.13
Bair Hugger Blanket In Box	2/22/2017	10:10:50	3961	3270	1250	410	400	320	72.97
Bair Hugger Blanket In Box	2/22/2017	10:11:50	2370	1470	270	0	0	0	73.71
Bair Hugger Blanket In Box	2/22/2017	10:12:50	2170	1190	320	0	0	0	74.34
Bair Hugger Blanket In Box	2/22/2017	10:13:50	1930	1370	360	0	0	0	74.95
Bair Hugger Blanket In Box	2/22/2017	10:14:50	2120	1260	270	0	0	0	75.33
Bair Hugger Blanket In Box	2/22/2017	10:15:50	2270	1230	350	0	0	0	75.72

Bair Hugger Blanket In									
	2/22/2017	10:16:50	2250	1280	320	10	0	0	75.96
Box	2/22/2017	10:17:50	50	50	70	50	170	300	73.18
Zero Particle Counter	2/22/2017	10:18:50	0	0	0	0	0	0	72.16
Zero Particle Counter	2/22/2017	10:19:50	0	0	0	0	0	0	71.74
Zero Particle Counter	2/22/2017	10:20:50	10	0	0	0	0	0	71.49

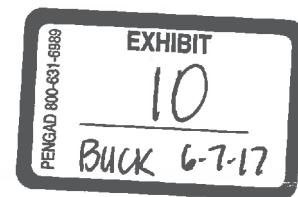
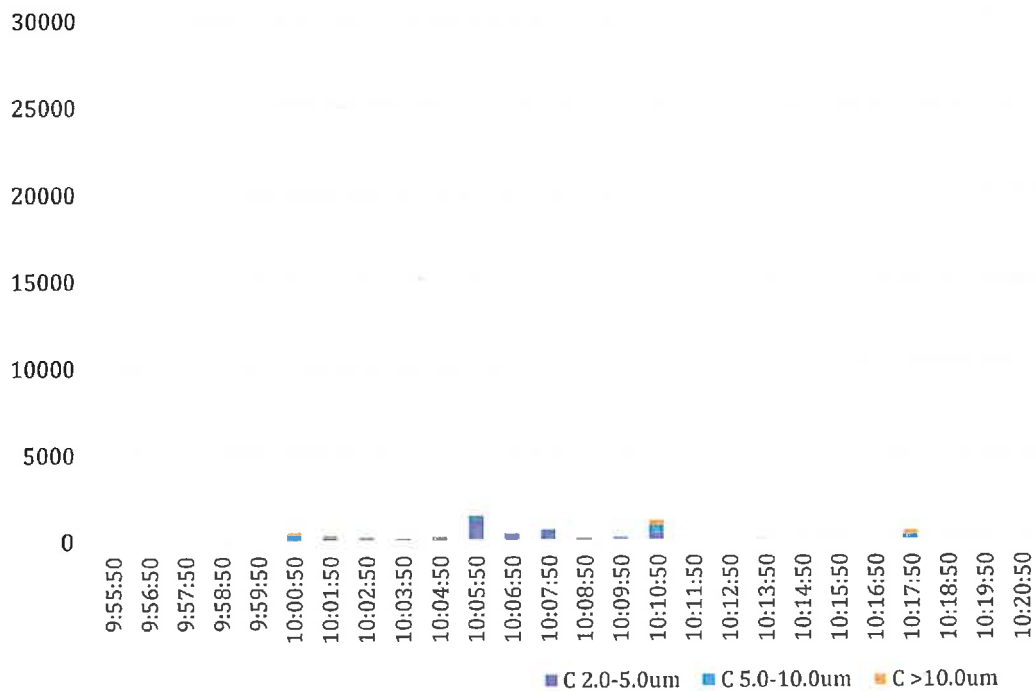
# **EXHIBIT DX51**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS

## Old Bair Hugger Blanket Test Inside Clean Room



## New Bair Hugger Blanket Test Inside Clean Room



# **EXHIBIT DX52**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS

# Airborne Respiratory Diseases and Mechanical Systems for CONTROL OF MICROBES

**Airborne respiratory pathogens and diseases in health care facilities are numerous and dangerous. HVAC systems are critical in controlling them.**

**1** Airborne transmission of respiratory diseases in indoor environments remains a problem of indoor air quality (IAQ) with few engineering alternatives and for which performance goals and design parameters are unclear. The engineer who attempts to deal with microbial IAQ finds that pertinent microbiological information exists in abundance but not in easily digestible forms. This article summarizes the relevant literature of medical microbiology and aerobiology in a manner that engineers may find useful and informative and that will facilitate the design of HVAC systems intended to reduce the threat. The general principles presented here can be applied to any indoor environment, including office buildings, schools, residences, hospitals, and isolation wards.

## Origin of respiratory diseases

The first indoor environments, built by man over half a million years ago, included caves with leather-draped interiors, fur-carpeted tents, and huts covered with animal hides. Microbial predators existed from time immemorial, but transmission had always required direct contact because they could not tolerate the sunlight and temperature extremes outdoors. Man's cozy new habitats made it possible for these ancient parasites to survive short airborne trips between hosts.

Animal husbandry seems to have resulted in a number of pathogens jumping species and then becoming adapted to indoor transmission to the exclusion of outdoor transmission. These include rhinoviruses, diphtheria, TB, smallpox, measles, and influenza, which appear to have come variously from horses, cows, dogs, pigs, and chickens. Most contagious human pathogens have evolved to such dependence on man's habitats for

transmission that they lack any ability to survive outdoors for long.<sup>1</sup>

In contrast, the non-contagious pathogens, including the fungi, environmental bacteria, and some animal pathogens, have maintained the ability to survive in the environment. Even so, direct sunlight is rapidly fatal to almost anything but spores.<sup>1</sup>

## Classification of pathogens

Pathogens are any disease-causing microorganism, but the term applies to any microbial agent of respiratory irritation, including allergens or toxigenic fungi. Respiratory pathogens fall into three major taxonomic groups: viruses, bacteria, and fungi. The fungi and some bacteria, most notably the actinomycetes, form spores. Since spores are characteristically larger and more resistant to factors that will destroy viruses and bacteria, the engineer may find it more convenient to consider spores a definitive and separate category.

The single most important physical characteristic by which to classify airborne pathogens is size since it directly impacts filtration efficiency.<sup>2</sup> Fig. 1 presents a graphic comparison of airborne respiratory pathogens in which the spores, bacteria, and viruses can be observed to differentiate well, based on size alone. The left axis indicates the "average" or typical diameter or width. The areas of the circles do not represent the actual sizes of the microbes, but each represents the diameter in proportion to one another. The span of diameters is seen to be almost four orders of magnitude. Some microbes are oval or rod-shaped, and for these only, the smaller dimension is indicated.

<sup>1</sup>Superscript numerals indicate references listed at end of article.

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# CONTROLLING MICROBES

Perhaps the most important classification is that of communicable versus non-communicable, a distinction that has both medical and engineering relevance. The term *communicable* is synonymous with the term *contagious*. Communicable diseases come mainly from humans, while non-communicable diseases hail mostly from the environment. However, many microbes that are endogenous to humans or are environmentally common may cause opportunistic infections in those whose health has been compromised. These occur primarily as nosocomial, or hospital-acquired, infections. These three categories then define all airborne pathogens:

- Communicable
- Non-communicable
- Primarily nosocomial

Table 1 lists all respiratory pathogens under these three categories, along with major diseases, common sources, and average diameters. In the column identifying microbial group, the term *actinomycetes* refers only to the spore-forming actinomycetes. Some general observations can be made from these charts such as the fact that most contagious pathogens come from humans, most non-contagious pathogens come from the environment, and most primarily nosocomial infections tend to be endogenous. These tables are not necessarily inclusive since a number of pathogens, such as *E. coli*, *Bacillus subtilis*, and some other strains of *Legionella*, can, on rare occasions, cause respiratory disease or allergic reactions.<sup>3</sup> The abbreviation "spp." denotes that infections may be caused by more than one species of the genera but does not imply that all species are pathogenic.

Table 1 lists only respiratory pathogens, although non-respiratory pathogens can also be airborne. Certain infections of the skin or eyes, nosocomial infections of open wounds and burns, and contamination of medical equipment may occur by the airborne route. Although these types of infections have not been well studied, any pathogen that transmits

by the airborne route will be subject to the same principles and removal processes described in this article.

## Communicable diseases

Table 1 lists all the main respiratory diseases that can transmit between human hosts via the airborne route. Humans are the natural reservoir for most contagious pathogens but some notable exceptions exist. Pneumonic plague and Arenavirus epidemics originate with rodents or other mammals.<sup>1</sup> In regards to the mysterious origin of *Influenza*, humans apparently share the function of natural reservoir with birds and pigs, as strains of this virus periodically jump between species.<sup>3</sup>

*continued on page 37*

**Figure 1. Relative size of airborne respiratory pathogens.**

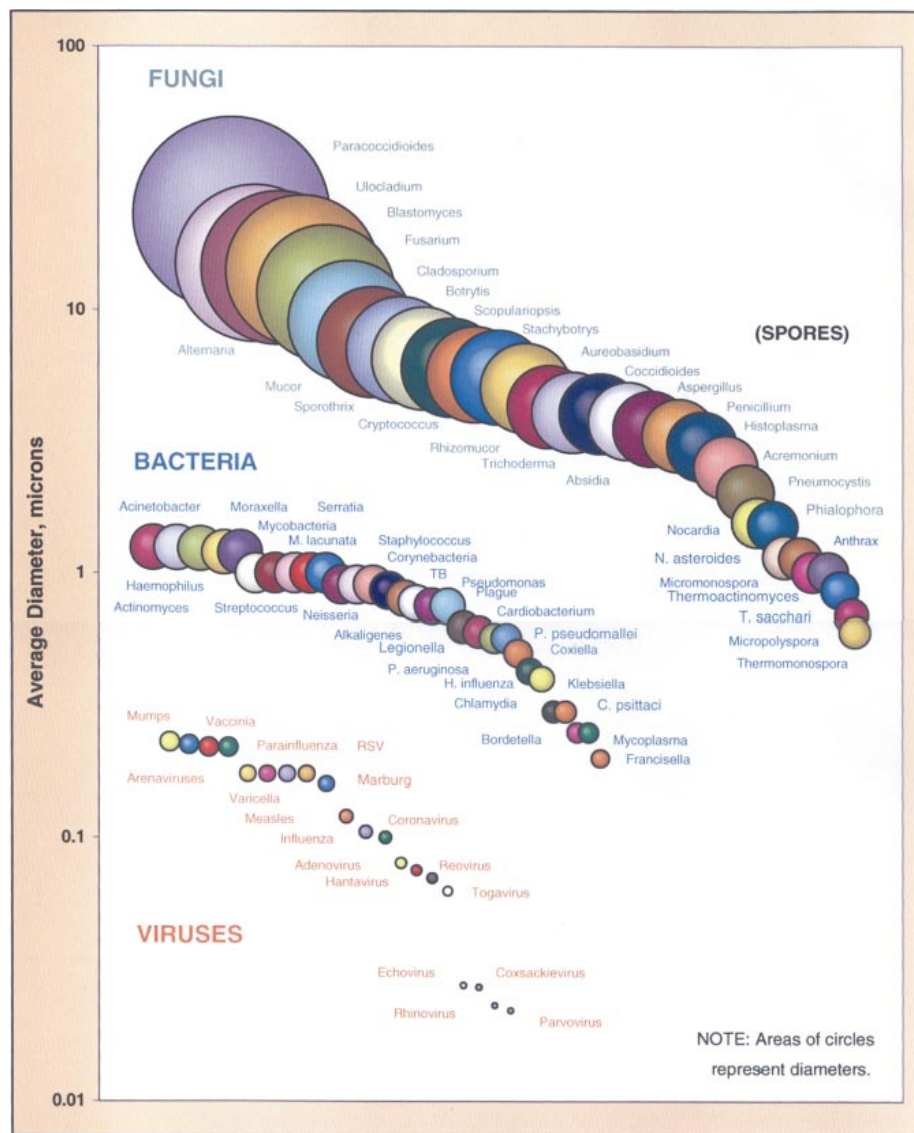


Table 1: Communicable Respiratory Pathogens

AIRBORNE PATHOGEN	MICROBIAL GROUP	DISEASE	SOURCE	Diameter microns	Notes
Adenovirus	VIRUS	colds	Humans	0.08	
Arenavirus	VIRUS	hemorrhagic fever	Rodents	0.18	F
Coronavirus	VIRUS	colds	Humans	0.11	
Coxsackievirus	VIRUS	colds	Humans	0.027	
Echovirus	VIRUS	colds	Humans	0.028	
Morbillivirus	VIRUS	measles (rubeola)	Humans	0.12	F, N
Influenza	VIRUS	flu	Humans, birds	0.1	F, N
Parainfluenza	VIRUS	flu	Humans	0.22	N
Paramyxovirus	VIRUS	mumps	Humans	0.23	F, N
Parvovirus B19	VIRUS	fifth disease, anemia	Humans	0.022	F
Reovirus	VIRUS	colds	Humans	0.075	
Respiratory Syncytial Virus	VIRUS	pneumonia	Humans	0.22	F, N
Rhinovirus	VIRUS	colds	Humans	0.023	
Togavirus	VIRUS	rubella (German measles)	Humans	0.063	N
Varicella-zoster	VIRUS	chickenpox	Humans	0.16	N
Chlamydia pneumoniae	BACTERIA	pneumonia, bronchitis	Humans	0.3	N
Mycobacterium tuberculosis	BACTERIA	TB	Humans	0.86	F, N
Yersinia pestis	BACTERIA	pneumonic plague	Rodents	0.75	F

Table 1: Primarily Nosocomial Respiratory Pathogens

AIRBORNE PATHOGEN	MICROBIAL GROUP	DISEASE	SOURCE	Diameter microns	NOTES
Acinetobacter	BACTERIA	opportunistic infections	Environmental	1.3	E, N
Actinomyces israelii	BACTERIA	actinomycosis	Humans	1.0	E, N
Alkaligenes	BACTERIA	opportunistic infections	Humans	0.75	E, N
Bordetella pertussis	BACTERIA	whooping cough	Humans	0.25	E, N
Cardiobacterium	BACTERIA	opportunistic infections	Humans	0.63	E, N
Corynebacteria diphtheria	BACTERIA	diphtheria	Humans	1.0	E, N
Haemophilus influenzae	BACTERIA	meningitis, pneumonia	Humans	0.43	E, N, F
Haemophilus parainfluenzae	BACTERIA	opportunistic infections	Humans	1	E, N
Klebsiella pneumoniae	BACTERIA	opportunistic infections	Environmental	0.4	E, N
Moraxella catarrhalis	BACTERIA	opportunistic infections	Humans	1.3	E, N
Moraxella lacunata	BACTERIA	opportunistic infections	Humans	1	E, N
Mycobacterium avium	BACTERIA	cavitary pulmonary dis.	Environmental	1.2	N
Mycoplasma pneumoniae	BACTERIA	pneumonia	Humans	0.25	E, N
Neisseria meningitidis	BACTERIA	meningitis	Humans	0.8	E, N, F
Pseudomonas aeruginosa	BACTERIA	opportunistic infections	Environmental	0.57	N
Pseudomonas mallei	BACTERIA	opportunistic infections	Environmental	0.77	N
Pseudomonas pseudomallei	BACTERIA	opportunistic infections	Environmental	0.57	N
Serratia marcescens	BACTERIA	opportunistic infections	Environmental	1.3	E, N
Staphylococcus aureus	BACTERIA	opportunistic infections	Humans	1	E, N
Streptococcus pneumoniae	BACTERIA	pneumonia, otitis media	Humans	0.9	E, N, F
Streptococcus pyogenes	BACTERIA	scarlet fever, pharyngitis	Humans	0.9	N
Pneumocystis carinii	Protozoa / Fungi	pneumocystosis	Environmental	2	S, N
Cryptococcus neoformans	FUNGI	cryptococcosis	Environmental	5.5	S, N

## NOTES:

E = Endogenous, common as human flora  
 F = Fungus occur (excluding nosocomial)  
 HP = Hypersensitivity Pneumonitis  
 N = Nosocomial, common as (purple blocks)

EAA = EXTRINSIC ALLERGIC ALVEOLITIS  
 S = Spore  
 VOC = volatile Organic Compounds produced  
 References: 4, 8, 17, 18, 22

Table 1: Non-Communicable Respiratory Pathogens

AIRBORNE PATHOGEN	MICROBIAL GROUP	DISEASE common (potential)	SOURCE	Diameter microns	NOTES
Hantavirus	VIRUS	hantavirus	Rodents	0.07	F
Poxvirus - Vaccinia	VIRUS	cowpox	Agricultural	0.23	
Bacillus anthracis	BACTERIA	anthrax	Cattle, sheep	1.1	S, F
Chlamydia psittaci	BACTERIA	psittacosis	Birds	0.3	
Coxiella burnetii	BACTERIA	Q fever	Cattle, sheep	0.5	
Francisella tularensis	BACTERIA	tularemia	wild animals	0.2	F
Legionella pneumophila	BACTERIA	LD, Pontiac fever	Environmental	0.6	F, N
Mycobacterium intracellulare	BACTERIA	cavitary pulmonary dis.	Environmental	1.2	
Mycobacterium kansasii	BACTERIA	cavitary pulmonary dis.	unknown	0.86	
Micromonospora faeni	ACTINOMYCETES	Farmer's Lung, HP	Agricultural	1	S
Micropolyspora faeni	ACTINOMYCETES	Farmer's Lung, HP	Agricultural	0.69	S
Nocardia asteroides	ACTINOMYCETES	nocardiosis	Environmental	1.1	S, N
Nocardia brasiliensis	ACTINOMYCETES	pulmonary mycetoma	Environmental	1.5	S, N
Nocardia caviae	ACTINOMYCETES	nocardiosis	Environmental	1.5	S, N
Thermoactinomyces sacchari	ACTINOMYCETES	bagassosis, HP	Agricultural	0.86	S
Thermoactinomyces vulgaris	ACTINOMYCETES	Farmer's Lung, HP	Agricultural	1	S
Thermomonospora viridis	ACTINOMYCETES	Farmer's Lung, HP	Agricultural	0.6	S
Absidia corymbifera	FUNGI	zygomycosis	Environmental	3.8	S
Acremonium spp.	FUNGI	(EAA)	Environmental	2.5	S
Alternaria alternata	FUNGI	mycotoxicosis	Environmental	14.4	S
Aspergillus spp.	FUNGI	aspergillosis, VOC	Environmental	3.5	S, N
Aureobasidium pullulans	FUNGI	chromomycosis, EAA	Environmental	5	S
Blastomyces dermatitidis	FUNGI	blastomycosis	Environmental	14	S, N
Botrytis cinerea	FUNGI	EAA	Environmental	7	S
Chaetomium globosum	FUNGI	chromomycosis, VOC	Environmental	5.5	S
Cladosporium spp.	FUNGI	chromoblastomycosis	Environmental	9	S
Coccidioides immitis	FUNGI	coccidioidomycosis	Environmental	4	S, N
Emmericella nidulans	FUNGI	(mycotoxicosis)	Environmental	3.3	S
Epicoccum nigrum	FUNGI	(EAA)	Environmental	20	S
Eurotium spp.	FUNGI	EAA	Environmental	5.8	S
Exophiala jeanselmei	FUNGI	chromomycosis	Environmental	2.0	S
Fusarium spp.	FUNGI	mycotoxicosis, VOC	Environmental	11.5	S
Geomyces pannorum	FUNGI	EAA	Environmental	3	S
Helminthosporium	FUNGI	EAA	Environmental	12.5	S
Histoplasma capsulatum	FUNGI	histoplasmosis	Environmental	3	S, N
Mucor plumbeus	FUNGI	mucormycosis	Environmental	7.5	S, N
Paecilomyces variotii	FUNGI	mycotoxicosis	Environmental	3	S
Paracoccidioides brasiliensis	FUNGI	paracoccidioidomycosis	Environmental	23	S
Penicillium spp.	FUNGI	mycotoxicosis, VOC	Environmental	3.3	S
Phialophora spp.	FUNGI	chromomycosis	Environmental	1.5	S
Phoma spp.	FUNGI	mycotoxicosis	Environmental	3.3	S
Rhizomucor pusillus	FUNGI	zygomycosis	Environmental	4.3	S
Rhizopus stolonifer	FUNGI	zygomycosis	Environmental	8	S, N
Rhodotulula spp.	FUNGI	(EAA)	Environmental	14	S
Scopulariopsis spp.	FUNGI	onychomycosis	Environmental	6	S
Sporothrix schenckii	FUNGI	sporotrichosis	Environmental	6.5	S
Stachybotrys spp.	FUNGI	stachybotryotoxicosis	Environmental	5.7	S, F
Trichoderma spp.	FUNGI	mycotoxicosis, VOC	Environmental	4.1	S
Ulocladium spp.	FUNGI	EAA	Environmental	15	S
Wallemia sebi	FUNGI	EAA	Environmental	3	S

## MICROBES

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Many contagious respiratory pathogens also transmit by direct contact through the exchange of infectious droplets or particles called fomites.<sup>4</sup> The eyes and nasal passages are vulnerable to fomite transmission. The predominance of these direct routes in comparison with the inhalation route has not been well established but can be very species-dependent.<sup>5</sup> Infectivity is also lost upon drying, and therefore hand or surface contact may require the exchange of moisture as well as an infectious dose.<sup>1,6</sup>

Barely 20 pathogens account for the overwhelming number of contagious respiratory infections. Table 2 lists the characteristics of these infections, while the typical course of these infections is depicted in Fig. 2. The infection rate refers to the fraction of those exposed to an infectious dose who contract the disease. This type of information can be useful to engineers attempting risk assessment or procedural control of infectious occupants or patients. Few infectious doses have been established, but for purposes of making rough or conservative estimations, as few as 1-10 TB bacilli can be infectious for humans—while a total of 200 Rhinovirus virions may be required to cause a cold.<sup>4</sup>

Most respiratory parasites induce their hosts to aerosolize large quantities of infectious bioaerosols by nasopharyngeal irritation, which causes coughing and sneezing.<sup>4,5</sup> Consider the profiles of the particle sizes shown in Fig. 3. A single sneeze can generate a hundred thousand floating bioaerosol particles, and many may contain viable microorganisms.<sup>7</sup> A single cough typically produces about one percent of this amount, but coughs occur about 10 times more frequently than sneezes.<sup>7</sup> Bioaerosols produced by talking are negligible, but extended shouting and singing can transmit infections.

Some limited data from Duguid<sup>7</sup> is available in generation rates stating that A TB infective can produce 1-249 bacilli per hr,<sup>8</sup> while a person in the infectious stage of a cold may produce 6200 droplet nuclei per hr containing viable viruses that remain airborne longer than 10 min. In one measles epidemic, 5480 virions were generated per hr.<sup>8</sup>

The dose received from an airborne concentration of microbes could be considered a factor under engineering control since it

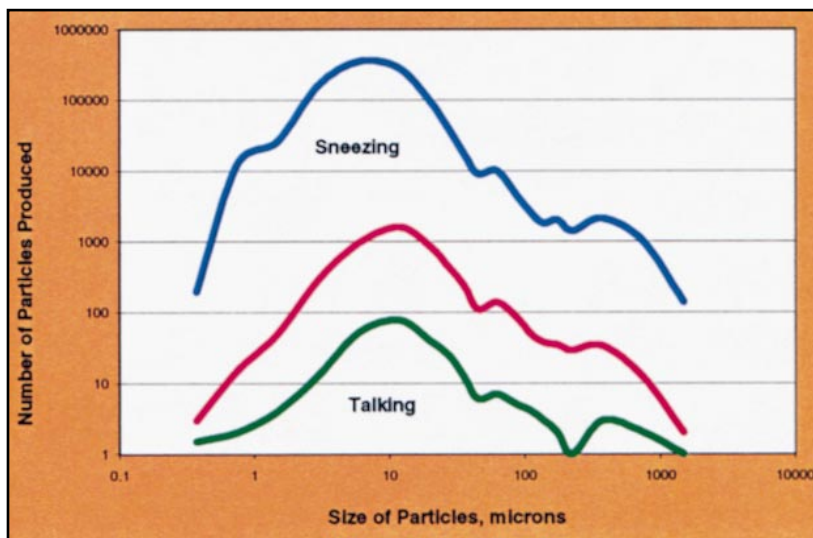
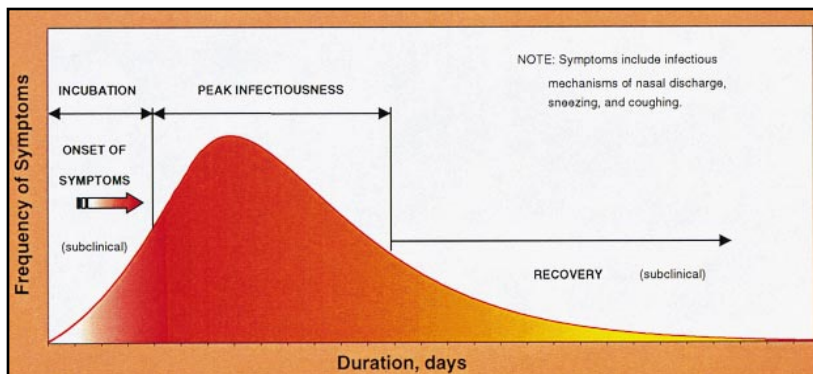
# CONTROLLING MICROBES

PATHOGEN		Common Disease	Annual Cases (U.S.)	Average Incubation (days)	Infectious Peak (days)	Maximum Duration (days)	Infection Rate (fraction)
VIRUS	BACTERIA						
Adenovirus		colds	*	4	4-9	19	0.51-0.75
Coronavirus		colds	*	3	(3-4)	18	0.45-0.5
Coxsackievirus		colds	*	3	3-12	20	0.53-0.64
Echovirus		colds	*	3	(3-4)	18	0.43-0.80
Influenza		flu	200000*	2	2-7	21	0.2-0.8
Morbillivirus		measles	25000	12	8-16	29	0.85
Parainfluenza		flu	*	3	3-12	21	0.2-0.75
Paramyxovirus		mumps	10000	17	10-26	39	0.6-0.85
Parvovirus B19		fifth disease	-	8	7-14	28	0.3-0.6
Respiratory Syncytial Virus		pneumonia	*	2	5-7	14	0.5-0.9
Rhinovirus		colds	*	2	2-7	7	0.38-0.89
Togavirus		rubella	3000	17	24-31	31	0.3-0.8
Varicella-zoster		varicella	*	16	12-20	25	0.75-0.96
Bordetella pertussis		whooping cough	2000	8	15-22	42	high
Chlamydia pneumoniae		pharyngitis	-	7	7-21	28	0.5
Corynebacteria diphtheria		diphtheria	490000	3	2-10	10	varies
Haemophilus influenzae		meningitis	8000	3	3-4	(14)	0.2-0.5
Mycobacterium tuberculosis		TB	21000	28	varies	-	0.33
Neisseria meningitidis		meningitis	4500	3	3-4	(21)	high
Streptococcus pneumoniae		pneumonia	500000	2	(2-10)	21	0.1-0.3
Yersinia pestis		pn. plague	14	2	2-3	3	varies

References 4, 8, 10, 17, 22

\*(Common respiratory infections are often not reported.)

**Figure 2. Generic curve for duration of symptoms of respiratory infections**



- Susceptibility of the individual (immunity).
- Duration of exposure.
- Concentration of infectious agent.
- Virulence of infectious agent.
- Breathing rate.
- Route of infection (inhalation, eyes, nasopharynx, etc.).

None of these factors is necessarily an absolute determinant. Health and degree of immunity can be as important as the dose received from prolonged exposure.

Computations of infectious airborne doses can be fraught with uncertainty. Epidemiological studies on colds avoid these problems by computing actual risks. Fig. 4 shows how duration and proximity to an infectious person can increase the likelihood of infection, based on data from Lidwell's studies of the common cold.<sup>9</sup> These data suggest that there may be a threshold distance beyond which risk decreases sharply. This risk may result from local airborne concentrations but may also include the risk of contact with fomites.

## Non-communicable diseases

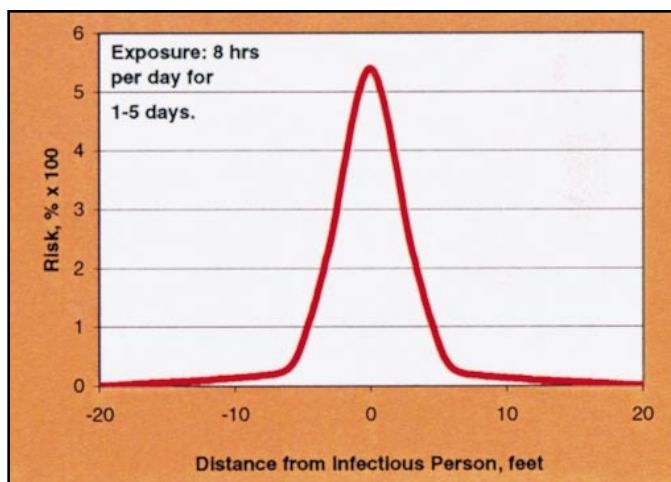
The list of non-communicable pathogens in Table 1 includes all known that cause respiratory infections, allergic reactions, and toxic reactions. Included among the diseases are EAA and HP (see notes),

*continued on page 40*

**Figure 3. Profile of particle sizes produced by an infectious person.**

*Based on data from Duguid et al 1945.*

## CONTROLLING MICROBES



**Figure 4. Risk of cold infection from proximity. Risk at zero represents intimate (husband-wife) contact.** Estimated per data from Lidwell.<sup>9</sup>

continued from page 38

which are sometimes associated with sick building syndrome (SBS). Non-communicable infections are almost entirely due to fungal or actinomycete spores and environmental or agricultural bacteria.

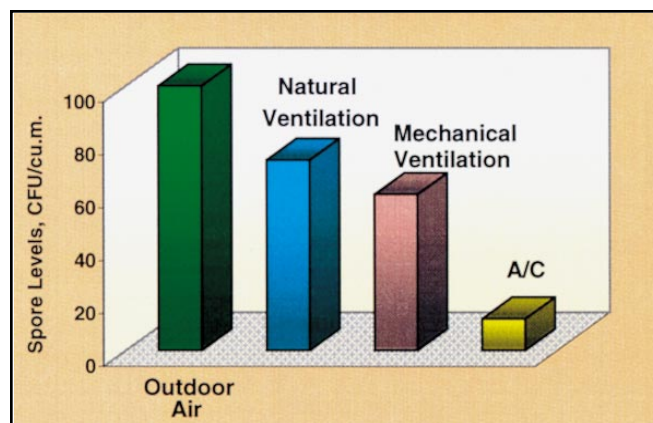
Spores form the most important group of non-communicable diseases. Outdoor spore levels vary with season and climate and can reach very high levels when dry, windy conditions result in disturbance of the soil where fungi grow. Surprisingly, few cases of respiratory infection have ever been attributed to inhalation of outdoor air,<sup>4,5</sup> probably because most people, especially Americans and Europeans, spend over 90 percent of their time indoors.<sup>10</sup> A small proportion of actinomycete infections have occurred outdoors

in agricultural facilities, although most tend to occur inside barns and workshops.<sup>11,12</sup>

Indoor air spore levels can differ from outdoor air in both concentration and composition of spores. In normal, dry buildings, spore levels tend to be anywhere from 10 to 100 percent of outdoor spore levels<sup>11</sup> and are mostly less than 200 colony forming units (CFU) per cu meter. Problem-free, multi-story office buildings typically have levels that are 10 to 31 percent of the outdoor air<sup>11</sup> levels. The composition of fungal species indoors tends to reflect that of the outdoors.<sup>13</sup> Some fungal species, most notably *Aspergillus* and *Penicillium*, are often found to account for 80 percent of indoor spores.<sup>10</sup>

Spores will germinate and grow in the presence of moisture and nutrients<sup>13</sup> in locations such as basements, drain pans, and on refrigerator coils. As a result of such growth, spores can be generated internally in problem buildings, wet buildings, and certain agricultural facilities at a high enough rate to cause indoor spore levels to exceed outdoor levels. If spore concentrations indoors consistently exceed

**Figure 5. Indoor spore levels by ventilation system type.** From the California Healthy Buildings Study.<sup>11</sup>



**Table 3: Microbial Levels in Indoor and Outdoor Air**

( Suggested Guidelines, Upper Limits, Average or Representative Levels )

Microbe	Lower Limit CFU/cu.m.	Average Range		Upper Limit	Qualification	I/O Ratio		Reference
		Low	High			Low	High	
Indoor Fungal Spores* (summer)	50	10	500	150		0.1	0.33	20, 23(ACGIH), 25(CG)
Outdoor Fungal Spores	100	100	1000	-		-	-	25(CG)
Actinomycete Spores	0	0	150	240	normal homes	-	-	23(Nevalainen), 25
Outdoor Actino. Spores	0	4	-	-	farmhouses	-	-	23 (Heineman)
Bacteria, non-pathogenic	50	0	500	50		0.26	1.1	10, 23, 25(ACGIH)
Outdoor Bacteria	-	179	1083	-		-	-	9(Brickus), 23
Pathogenic Bacteria	0	-	-	0				20(AIHA)
Viruses	0	-	-	0				20(AIHA)

\*(when species mix reflects outdoor air)  
CG: Canadian Guidelines

ACGIH: American Conference of Government Industrial Hygienists  
AIHA: American Industrial Hygiene Association  
CHBS: California Healthy Buildings Study

outdoor levels, the building can be inferred to contain an indoor amplifier.<sup>14</sup>

In the California Healthy Buildings Study,<sup>11</sup> naturally ventilated, mechanically ventilated, and air conditioned buildings all had lower indoor spore levels than the outdoors (Fig. 5). However, Fig. 5 may reflect favorable local conditions since many studies have measured much higher levels than these in non-problem buildings.

Table 3 lists the results of various studies that include measurements of outdoor spore levels and typical, average, or representative indoor levels. These levels do not necessarily pose a health threat. Measurements and guidelines vary almost as widely as outdoor levels vary seasonally and geographically.

Microorganisms will take advantage of any opportunity to establish themselves and multiply in a new environment.<sup>4</sup> Niches for microbial growth may be created inadvertently by engineered systems that generate moisture such as humidifiers, evaporative air coolers, cooling coil drain pans, and condensation on ductwork insulation. Amplification may result in airborne concentrations above the outdoors<sup>10</sup> and may reach unhealthy levels.<sup>13</sup> Legionnaire's Disease provides a sentinel example of pathogenic microbial amplification by an engineered system.

Amplifying factors can be controlled through various means, including preventive design through humidity and moisture control. Some other first and second line defensive measures include filtration, the removal of materials that provide nu-

trients, procedural cleaning and maintenance, and the use of biocidal equipment.

Table 4 identifies fungal pathogens that have been found to grow indoors on various surfaces or in HVAC equipment. Unidentified multiple species (spp.) may

**Table 4: Fungi That May Grow Indoors**

Airborne Pathogen	Indoor Growth		HVAC Equipment Growth	
	Location	Reference	Location	Reference
<i>Acremonium spp.</i>			humidifier water	Heineman (23)
			HVAC fiberglass insulation	(19)
<i>Alternaria spp.</i>	indoors > outdoors	(2)	cooling systems	(11)
	paint mildew	(26)	refrigerator coils	(21)
	carpet dust	Gravesen (23)	filters	Shata (9), (12)
	floor dust	Hoekstra (23)	filters	Neumeister (16)
<i>Aspergillus spp.</i>			dust in ductwork	Valbjorn (9)
	indoors > outdoors	(2)	evaporative air cooler	(16)
	carpet dust	Gravesen (23)	HVAC fiberglass insulation	(19)
	floor dust	Hoekstra (23)	cooling systems, coils	(11), (30)
<i>Aureobasidium pullulans</i>			fans, filters	Heineman (23), (12)
			dust in ductwork	Sugawara (16)
	moist building materials	Pasanen (23)	filters	Shata (9)
	latex painted surfaces	(26)		
<i>Chaetomium spp.</i>			HVAC fiberglass insulation	(19)
			filters	Heineman (23)
			dust in ductwork	Valbjorn (9)
<i>Cladosporium spp.</i>	wet carpet, wet walls	(21)	evaporative coolers	(11)
	moist building materials	Pasanen (23)	HVAC fiberglass insulation	(19)
	latex painted surfaces	(26)	filters	Shata (9)
	floor dust	Hoekstra (23)	HVAC metal surfaces	(1)
	carpet dust	Gravesen (23)	fans, filters	Heineman (23)
			ductwork dust	Sugawara (16)
<i>Cryptococcus spp.</i>	floor dust	Hoekstra (23)		
<i>Epicoccum spp.</i>	indoors > outdoors	Kemp (16)	fiberglass insulation	Morey (9)
<i>Eurotium herbariorum</i>	gypsum-based finishes	Adan (23)		
<i>Exophiala spp.</i>			humidifier water	Heineman (23)
<i>Fusarium spp.</i>	indoors > outdoors	Fouad (16)	filters	Neumeister (16)
	floor dust	Hoekstra (23)	humidifier water	Heineman (23)
<i>Helminthosporium</i>	indoors > outdoors	Kemp (16)		
<i>Mucor spp.</i>	indoors > outdoors	Kemp (16)	fans, filters	Heineman (23), (12)
	floor dust	Hoekstra (23)	dust in ductwork	Valbjorn (9)
<i>Paecilomyces spp.</i>			humidifier water	Heineman (23)
<i>Penicillium spp.</i>	indoors > outdoors	(2)	air conditioners	(11)
	latex painted surfaces	(26)	evaporative air cooler	(16)
	carpet dust	Gravesen (23)	HVAC ducts	(5)
			filters	Pasanen (23), (12)
			fans, humidifier water	Heineman (23)
<i>Phialophora spp.</i>			humidifier water	Heineman (23)
<i>Phoma spp.</i>	paint mildew	(26)	filters	Neumeister (16)
	floor dust	Hoekstra (23)	humidifier water	Heineman (23)
<i>Rhizopus spp.</i>	floor dust	Hoekstra (23)	fans	Heineman (23)
			filters	Neumeister (16)
			dust in ductwork	Valbjorn (9)
<i>Rhodotulula spp.</i>	wet carpet, wet walls	(21)		
	indoors > outdoors	Kemp (16)		
<i>Scopulariopsis spp.</i>	floor dust	Hoekstra (23)	filters	Heineman (23)
<i>Stachybotris spp.</i>	building materials	Scott (16)	fans, humidifier water	Heineman (23)
	moist building materials	Pasanen (23)		
<i>Trichoderma spp.</i>	indoors	(7)	fans	Heineman (23)
	moist building materials	Pasanen (23)	filters	Neumeister (16)
			ductwork dust	Sugawara (16)
<i>Ulocladium spp.</i>	floor dust	Hoekstra (23)	filters	Neumeister (16)
			humidifier water	Heineman (23)
<i>Wallemia sebi</i>	floor dust	Hoekstra (23)	filters	Shata (9)

not necessarily be pathogenic. Many factors may dictate which pathogens will grow indoors such as climate, indoor materials, degree of human occupancy, hygiene, and moisture levels.<sup>1,8</sup>

Table 5 identifies some pathogenic environmental bacteria that have been found growing indoors or on HVAC equipment. Occasionally, some contagious bacteria disseminated from hu-

## C O N T R O L L I N G M I C R O B E S

mans can be found in water, equipment, or in dust, but these are transient occupants and unlikely to grow or survive long outside of human hosts.<sup>1,5</sup>

### Nosocomial infections

All respiratory pathogens are potentially nosocomial, but those that occur almost exclusively as nosocomial infections are listed in Table 1 such as primarily nosocomial respiratory pathogens.

Table 5: Bacteria That May Grow Indoors

Airborne Pathogen	Location of Growth	Reference
<i>Acinetobacter</i>	potable water	Highsmith (14)
<i>Klebsiella pneumoniae</i>	potable water	Highsmith (14)
<i>Legionella pneumophila</i>	potable water	(22)
	cooling towers	(14)
<i>Micropolyspora faeni</i>	home humidifiers	(7)
<i>Pseudomonas aeruginosa</i>	indoors	Strom (9)
	indoor dust	(18)
	potable water	Highsmith (14)
	evaporative air cooler	(16)
	humidifiers	(7)
<i>Pseudomonas spp.</i>	filters	Martikainen (9)
<i>Serratia Marcescens</i>	potable water	Highsmith (22)
<i>Thermoactinomyces vulgaris</i>	air conditioners	(7)
	humidifier water	Heineman (23)

The other common nosocomial infections are identified with a purple boxed *N* in the notes column.

In intensive-care units, almost a third of nosocomial infections are respiratory, but not all of these are airborne since some are transmitted by contact or by intrusive medical equipment.<sup>15</sup> Nosocomial infections can also be airborne but non-respiratory such as when common microbes like *Staphylococcus* settle on open wounds, burns, or medical equipment.

Patients who succumb to nosocomial infections are often those whose natural defenses have been compromised either as a result of disease, medication, injury, or bypassed by intrusive procedures. In cases of immune system deficiency, even a patient's own endogenous flora could cause infection, while normally benign environmental microbes can become pathogenic.

The protection of patients from potential pathogens requires the reduction of microbial contaminants below normal or ambient levels. This is usually accomplished through the use of isolation rooms, HEPA filters, UVGI, and strict hygiene procedures.<sup>15</sup> In the health care environment, particular attention must be paid to the possibility of microbial growth indoors and in the air handling units, even if levels are not a threat to healthy

people. Low-level indoor microbial amplification in health care settings may cause building-related illness (BRI) without actually representing SBS.

Technically, nosocomial infections relate to those who are hospitalized, but health care professionals themselves may be at risk. The Center for Disease Control (CDC) publishes guidelines for control of infections<sup>15</sup> among hospital employees, but appropriate engineering design and maintenance can play a significant role in reducing the risks for medical professionals as well as for patients.

### Natural microbial decay

Various environmental factors destroy airborne microbes.<sup>1</sup> Direct sunlight contains lethal levels of ultraviolet radiation. Dehydration renders most microbes inactive, although many spores may survive indefinitely. High temperatures will inactivate all pathogens, some more rapidly than others. Freezing will destroy most pathogens; except that some, especially spores, may be preserved. Oxygen slowly kills most airborne microorganisms through oxidation. Pollution levels that we tolerate our entire lives can be fatal to microorganisms. Plate-out, or adsorption, occurs on all interior building surfaces, but this removal rate tends to be negligible.

Each of these environmental processes reduces pathogen populations according to the following general equation:<sup>1,6</sup>

$$N = N_0 e^{-kt} \quad (1)$$

where

$N$  = population at time  $t$

$N_0$  = population at time  $t = 0$

$k$  = rate constant for process

$e = 2.718$

The resulting exponential decay curve is known as a survival curve, or death curve. Often, a very small fraction of the microbial population, usually about 0.01 percent, resists chemical or physical inactivation for extended periods of exposure.<sup>1,16</sup>

This relation applies additively to all reduction processes—except that humidity levels will influence the effects of other factors such as ultraviolet germicidal irradiation (UVGI) and heat on a species-dependent basis. In the outdoors, sunlight, temperature extremes, and wind ensure that non-spore microbial populations decay and disperse rapidly, generally within minutes.<sup>1,16</sup> In the indoors, these factors

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## CONTROLLING MICROBES

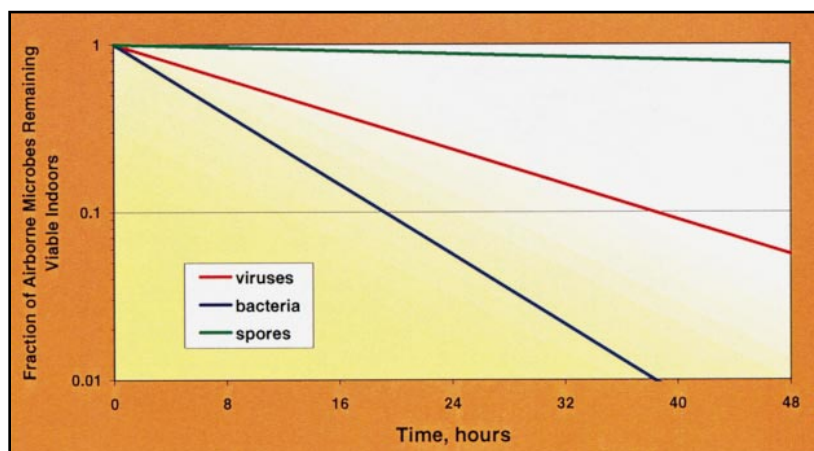
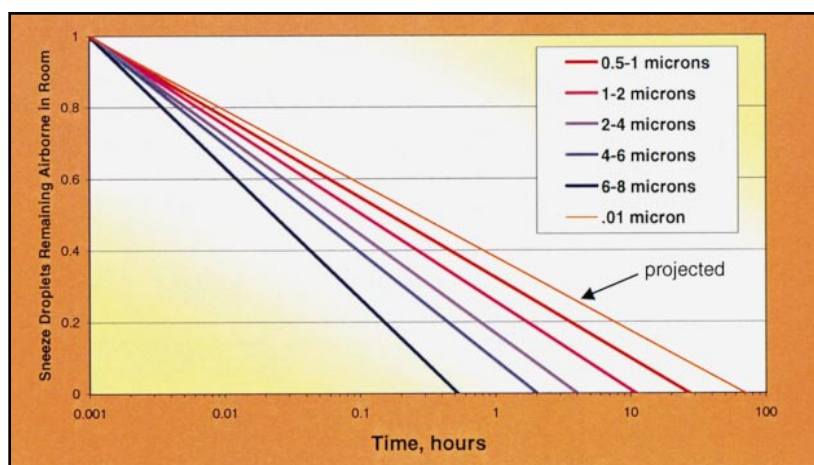
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are controlled for human comfort, resulting in airborne microbes surviving longer, sometimes even days.<sup>1,4</sup>

After expulsion by sneezing or coughing, most large droplets will settle out of the air within a matter of minutes. Fig. 6 illustrates this process and is based on fitted data. Many of the micron-sized droplets will rapidly evaporate to droplet nuclei that approach the size of the individual microbe. Micron-sized particles can remain suspended for hours and spread by diffusion or air currents.<sup>8</sup>

Airborne microbes lose viability over time. In the absence of sunlight, the decay rates for each microbial group, based on rates measured in a variety of studies,<sup>16</sup>

**Figure 6.**  
Disappearance of  
airborne sneeze  
droplets from room  
air by size. Based on  
fitted, normalized data  
from Duguid.<sup>7</sup>



**Figure 7.**  
Viability of airborne  
microbes indoors in  
absence of sunlight.

Based on averages for each  
microbial group.<sup>1,16</sup>

are shown in Fig. 7. Curiously, bacteria decay faster in air than viruses apparently because they depend more on moisture for their survival than do viruses.

### Pathways and dissemination

Fig. 8 illustrates some distinctions between airborne pathogens in relation to a

typical air handling unit (AHU). Contagious viruses and bacteria come almost exclusively from humans, and they will appear only in the return air. Spores and environmental bacteria may enter from the outdoors, but once growth (amplification) occurs indoors, they may appear in the return air at higher levels than in the outdoor air. Environmental bacteria are rarely pathogenic for healthy people (Table 1), but they may provide a nutrient source for pathogenic fungi.

Spores can initially enter a building by various routes, including inlet air or infiltration, or they may be brought in with building materials, carpets, clothes, food, pets, or potting soil. In a normal, dry building, the return air will have lower levels of spores than the outdoor air,<sup>11,12</sup> except when snow covers the ground and outdoor spore levels approach zero. When indoor amplifiers are present, the return air could be expected to contain higher levels of spores than the outdoor air, except during dry, windy, summer conditions when outdoor levels of spores can become very high.

Once spores germinate and growth occurs in an AHU or anywhere inside the building, new spores may be generated and appear in the return air. Filters may intercept spores, but moisture may cause them to “grow through” the filter media. Cooling coils can have a pronounced filtering effect on spores,<sup>11,12</sup> but the presence of condensation may also cause microbial growth and amplification<sup>10</sup> downstream of the coils, negating the effect.

Boosting outside air flow may be an option only if the ventilation system is not the source of microbial contamination; in which case, increasing air flow may exacerbate the problem.<sup>11</sup> A fungus problem that is not caused by the ventilation system, such as a leaky roof or wall, requires separate remedial action such as removing the damaged material.<sup>17</sup>

### Engineered alternatives

Natural decay mechanisms operate too slowly inside most buildings to prevent secondary infections.<sup>16</sup> Available engineering alternatives include purging with outside air, filtration, UVGI, and isolation through pressurization control. Each of these technologies has advantages and limitations, but optimization for any application is always possible if the microbial IAQ goals are clearly specified.

Pressurization control is commonly used in biohazard facilities and isolation rooms to prevent migration of microbes from one area to another, but inherent costs and operational instability at normal air flow rates limit feasibility for other applications.

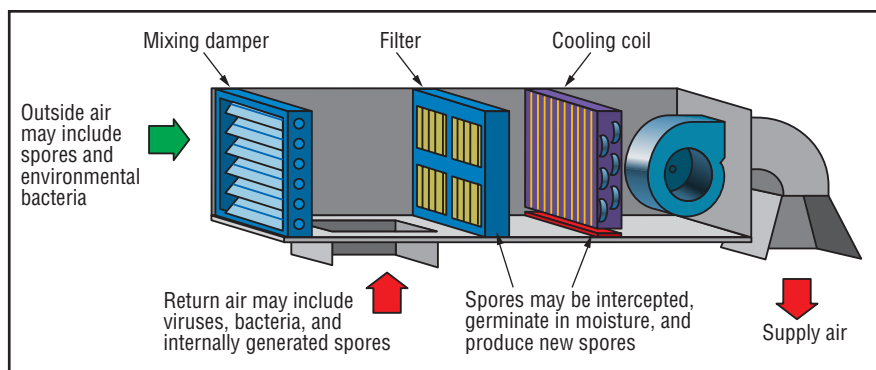
Full outside air systems are often used in health care facilities and TB isolation rooms, subject to CDC guidelines.<sup>15</sup> Fig. 9 shows the effect of full purge air flow on the reduction of pathogens in a room with an initial concentration of 100 microbe CFU per cu meter. Comparing this with Fig. 10 shows the results of HEPA filtration at the same recirculation flow rates. The results are practically identical.

The use of HEPA recirculation, of course, carries a lower total energy penalty<sup>2</sup> in hot or cold climates. But in mild or dry climates, high percentages of outside air can prove economical, especially in applications involving evaporative coolers. Hospitals often have commitments to specific guidelines, but other facilities may select and size systems to suit their goals and budgets.

HEPA filters, for example, are not the only choice for controlling microbial IAQ. High or medium efficiency filters are capable of removing airborne pathogens, especially spores, without high operation or replacement costs.<sup>2,16</sup> Overall, particle removal efficiency might be improved by locating medium efficiency filters in the recirculation loop vs. the outside air intakes<sup>16</sup> or even downstream of the cooling coils. But, this choice will depend on each individual system's operating parameters.

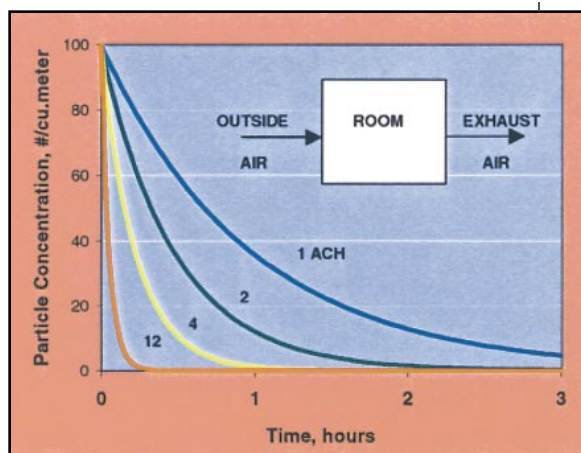
Combining purge air with HEPA filtration results in performance that is essentially additive, and cost optimization becomes straightforward. Energy consumption, replacement costs, and microbial IAQ goals will dictate the economic choice for any particular installation.<sup>16</sup> The performance of medium efficiency filters in combination with purge air flow is not directly additive but depends on the filter efficiency vs. particle size curves, the sizes of the pathogens of concern, and the system operating parameters.

UVGI can be an efficient method to use in the right applications such as controlling microbial growth in cooling coils.<sup>18</sup>

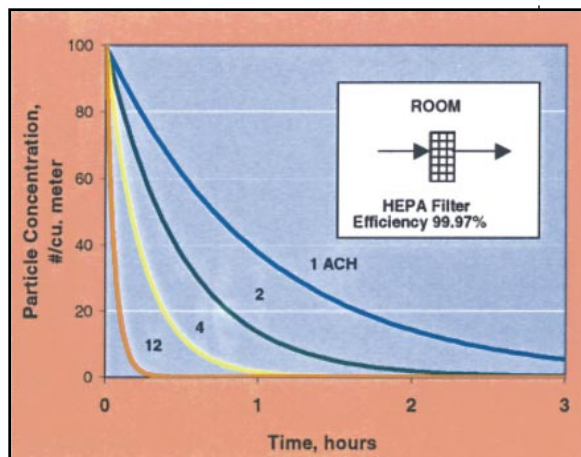


**Figure 8.** Sources and pathways of microbial contamination in a typical air handling unit.

The continuous exposure appears to inhibit fungal growth and may kill the spores as well. In applications involving the disinfection of air streams, the effectiveness of UVGI depends on factors that include air velocity, local air flow patterns, degree of maintenance, characteristic resistance of the microbes, and humidity.<sup>16</sup> A single pass through a UVGI system may have a limited effect, but recirculation, either through stand-alone units or ventilation systems, will result in multiple exposures or chronic dosing.



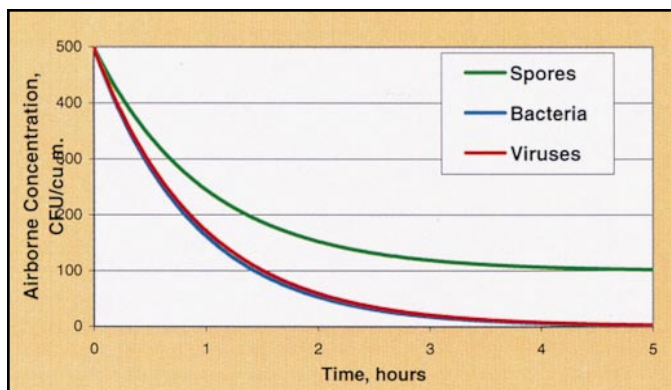
**Figure 9.** 100 percent outside air: effect of ach on reduction of initial level of room microbial contamination.



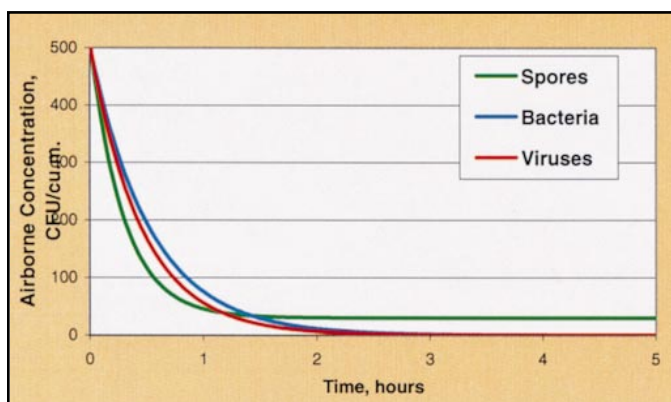
**Figure 10.** HEPA filter recirculation: effect of flowrate (in ach) on the reduction of initial level of room microbial contamination.

## CONTROLLING MICROBES

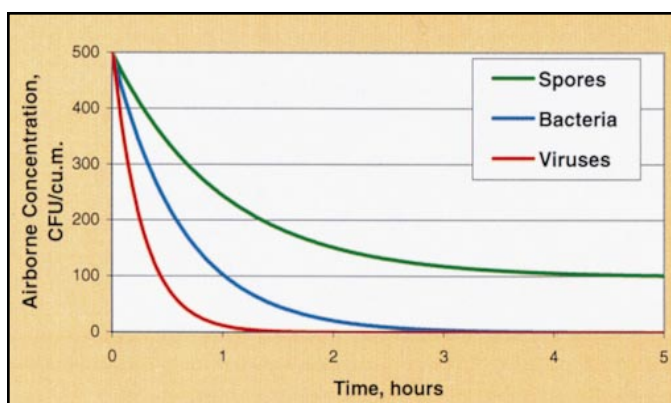
**Figure 11.**  
Effects of 25  
percent outside  
air (1 ach) on  
indoor contaminant  
levels.<sup>16</sup>  
Outdoor spore  
level = 100 cfu  
per cu meter.



**Figure 12.**  
Effect of  
ASHRAE filter,  
80 to 85 percent  
efficiency  
on indoor  
contaminant  
levels.<sup>16</sup>  
Recirculation  
with 25 percent  
outside air.



**Figure 13.**  
Effect of UVGI  
on indoor  
contaminant  
levels.<sup>16</sup> Re-  
circulation  
with 25 percent  
OA. UVGI power  
mW (W=watt)  
per sq cm



Chronic dosing with UVGI can have a major impact on airborne viruses and bacteria.<sup>16</sup>

A graphic comparison of the relative effectiveness of the three main alternatives—outside air purge, filtration, and UVGI—is provided in Fig. 11 through 13. Fig. 11 shows the effect of 1 air changer per hr (ach) of outside air on reduction of room air contaminant concentrations from an initial value. Perfect mixing is assumed, along with 500 CFU per cu meter contamination of each microbial group initially, 100 CFU per cu meter of spores in the outside air, and no internal generation. Natural decay rates from Fig. 7 are incorporated in the model. The scenario of an initially contaminated room may not be re-

alistic but provides dramatic differentiation of the effectiveness of pathogen removal.

Fig. 12 shows the effect of an ASHRAE medium efficiency filter (80 to 85 percent dust spot) to the supply air of the model building while maintaining 1 ach of outside air. The filter model describes filter efficiency vs. diameters in accordance with typical vendor performance curves.<sup>16</sup> Spore levels indoors are clearly reduced below outdoor ambient levels. Some reduction of bacteria and viruses can also be noted, but their removal is still dominated by the purging effect of the outside air. The filter used in this analysis provides a baseline for comparison. High efficiency filters, such as the 90 to 95 percent filters used in hospitals,<sup>2</sup> would result in even higher removal rates.

Fig. 13 shows the impact of a UVGI system with 25  $\mu$ W (W=watt) per sq cm placed in the recirculation loop. The outside air is maintained at 1 ach, but no filters are included. Spores are relatively unaffected by the UVGI, but the viruses are markedly reduced. This model incorporates chronic dosing effects from recirculation with an exposure of 0.2 sec for each pass. The decay rate Equation 1 is applied with known rate constants<sup>16</sup> for a wide cross-section of the microbial species listed in Table 1.

The unusual performance characteristics of each technology have been highlighted in these examples. Inclusion of these characteristics in any evaluation, along with the IAQ design goals, ambient conditions, and internal generation rates, will dictate the choices for any given application—subject only to economic limitations.

### Other alternatives

Various current or experimental technologies have the potential for reducing airborne disease transmission or indoor amplification. Biocidal filters can limit or prevent fungal growth on the filter media. Electrostatic filters (*i.e.*, electrets or electrically stimulated filters) are available but have not seen widespread

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use. Carbon adsorbers have pore sizes too small to remove viruses, but they are effective at removing VOCs produced by some fungi and bacteria.

Other technologies currently under research include low-level ozonation, negative air ionization, and photocatalytic oxidation—a technology that may one day result in a type of light-powered, self-cleaning, microbial filter.

### Conclusions

Perfect solutions to the problem of airborne disease transmission do not yet exist, but the available technologies—outside purge air, filtration, and UVGI—can be successfully implemented when their characteristic effects are understood and the goals clearly defined. Whether the application involves improvement of microbial IAQ in an office building or minimizing the risk of infection in an operating room, these technologies can be optimized individually or in combination from a cost or performance standpoint.

Finally, since microbes will never ignore opportunities provided to them, appropriate design, regular surveillance, and maintenance of these technologies in particular, and HVAC systems in general, should always be proactive.

HPAC

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# **EXHIBIT DX53**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS



# Monitoring air sampling in operating theatres: can particle counting replace microbiological sampling?

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## KEYWORDS

Environmental monitoring; Operating rooms; Air microbiology; Particle counting

**Summary** Microbiological contamination of air in the operating room is generally considered to be a risk factor for surgical site infections in clean surgery. Evaluation of the quality of air in operating theatres can be performed routinely by microbiological sampling and particle counting, but the relationship between these two methods has rarely been evaluated. The aim of this study was to determine whether particle counting could be predictive of microbiological contamination of air in operating rooms. Over a three-month period, air microbiological sampling and particle counting were performed simultaneously in four empty operating rooms belonging to two surgical theatres equipped with conventional ventilation via high-efficiency particulate air filters. Correlation between the two methods was measured with Spearman's correlation coefficient. The ability of particle counting to discriminate between microbiological counting values higher and lower than 5 colony-forming units (CFU)/m<sup>3</sup> was evaluated using receiver-operating characteristic (ROC) analysis. Microbiological counting ranged from 0 to 38 CFU/m<sup>3</sup>, while the particle counts ranged from 0 to 46 262/m<sup>3</sup>. Methods of microbiological and particle counting did not correlate (Spearman correlation coefficient=0.06,  $P=0.6$ ). Using the ROC curve, no particle count value could be predictive of a microbiological count higher than 5 CFU/m<sup>3</sup>. The results of the current study suggest that there is no reason to replace microbiological sampling with particle counting for routine evaluation of microbiological contamination in conventionally ventilated operating theatres.

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## Introduction

More than 20 years after the studies performed by Lidwell *et al.*,<sup>1,2</sup> microbiological contamination of air in operating theatres is generally considered to be a risk factor for surgical site infections, especially in clean surgery.<sup>3,4</sup> Thus, control of air contamination should be efficiently managed by infection control teams. At present, there is no international consensus on the most suitable method for routine air monitoring of filtered air hospital areas. Evaluation of the quality of air in operating theatres can be performed routinely by microbiological sampling and particle counting. Microbiological sampling, consisting of measuring the amount of micro-organisms in a determined air volume, is time consuming and results may be only available after several days. Conversely, measurement of particle counts is less demanding and offers immediate results, but the information delivered is indirect. The relationship between the two methods has rarely been evaluated in operating theatres.<sup>5,6</sup> The aim of this study was to determine whether particle counting could be predictive of microbiological contamination of air in operating theatres.

## Methods

### Sampling methods

Over a three-month period (15 March to 15 June 2003), microbiological air sampling and particle counting were performed simultaneously in four operating rooms belonging to two conventionally ventilated surgical theatres in a 700-bed university hospital in Paris, France. After filtration through prefilters followed by high-efficiency particulate air (HEPA) filters, air diffused into the operating room through a ventilated ceiling with low-speed air movement designed to achieve 30 air changes per hour. Microbiological air counts were measured using an impactor air sampler (Air-test Omega, LCB, France) at a flow rate of 100 L/min for 5 min (500 L) sampling on to Trypticase soy agar (BioMérieux, France), which was then incubated for four days at 30 °C. Air counts were expressed as colony-forming units (CFU) per m<sup>3</sup>. Particles (>0.5 µm) were counted by means of a particle analyser (Met One 227A, Pacific Scientific Instruments, Grants Pass, OR, USA) for 1 min at a flow rate of 2.8 L/min and expressed as number of particles per m<sup>3</sup>. Samples were obtained in three different locations in each empty operating room on eight different days.

Measurement of particles was done in triplicate at each location according to the manufacturer's instructions.

### Statistical methods

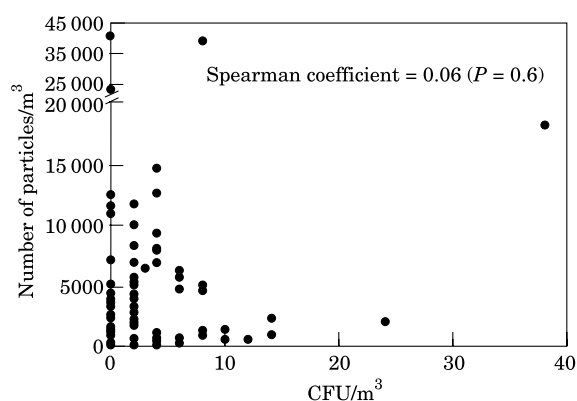
Log<sub>10</sub>-transformed particle counts were used because of log normal distribution of the variable. Data for this variable are expressed as geometric means and 95% confidence intervals. The three zero values for particle counts were arbitrarily set to 35, i.e. 50% of the minimum value. As colony count is a discrete variable, data for this variable are expressed as medians and interquartile ranges. Two methods were used to measure the degree of association between particle counts and colony counts. First, a scatterplot of particle counts and colony counts was drawn. The strength of this correlation was measured with the Spearman correlation coefficient. Secondly, the value of 5 CFU/m<sup>3</sup> was chosen as a critical value for microbiological count. We tried to find the best cut-off value of particle counting that could discriminate between high (>5) and low (<5) microbiological count values with high sensitivity and high specificity. The ability of particle counting to discriminate between microbiological counting values higher and lower than 5 CFU/m<sup>3</sup> was evaluated using receiver-operating characteristic (ROC) analysis.<sup>7</sup>

## Results

A total of 192 samples was analysed; 96 with the air sampler and 96 triplicate samples with the particle counter. Microbiological counting ranged from 0 to 38 CFU/m<sup>3</sup> [median (interquartile range)=2 (0, 4)], while the particle counts ranged from 0 to 46 262/m<sup>3</sup> [geometric mean (95% CI)=2311 (1724, 3096)]. Methods of microbiological counts and particle counts did not correlate (Spearman's correlation coefficient=0.06, *P*=0.6) (Figure 1). According to the ROC curve, no particle count value could be predictive of a microbiological count higher than 5 CFU/m<sup>3</sup> (area under curve=0.4868) (Figure 2).

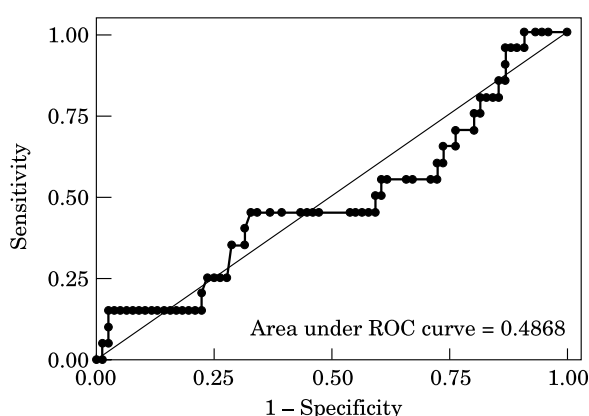
## Discussion

Quarterly routine surveillance of air contamination by microbiological sampling has been implemented in the two conventionally ventilated operating theatres since the hospital was opened in 2000.



**Figure 1** Relationship between particle counts and microbiological counts obtained in four operating rooms over a three-month period. CFU, colony-forming units.

However, this technique is time consuming and the question of its replacement by a faster and simpler method was considered. In a recent review, Dharan and Pittet recommended particle counting, a technique derived from industrial cleanroom technology standards, as a routine procedure instead of microbiological sampling for routine air monitoring in operating theatres.<sup>8</sup> However, the relationship between particle counting and microbiological sampling has rarely been evaluated in operating theatres. During surgical operations performed in an ultra-clean theatre, Seal and Clark demonstrated that particles sized 5–7  $\mu\text{m}$  correlated significantly with microbiological contamination.<sup>6</sup> In contrast, no correlation was observed between the bacterial and particle counts during operations performed in a conventionally ventilated operating theatre.<sup>5</sup> In the present study, we also observed an



**Figure 2** Receiver-operating characteristic (ROC) curve of particle counts to discriminate between microbiological count values higher and lower than 5 colony-forming units (CFU)/m<sup>3</sup>.

absence of correlation between the two methods in empty operating theatres equipped with conventional ventilation via HEPA filters. Many high values of particle counts were not associated with an increase in air microbiological counts, indicating that these particles were not of contaminated origin. The clinical significance of an increase in such air particle counts is therefore likely to be minimal. The cut-off value of 5 CFU/m<sup>3</sup> was specifically studied because it has been defined as the threshold limit in French guidelines.<sup>9</sup> Variable threshold limits for bacterial contamination in conventionally ventilated operating theatres have been set in different countries. For example, the limit has been set at 35 CFU/m<sup>3</sup> in the UK and 25 CFU/m<sup>3</sup> in hospitals in Geneva, Switzerland.<sup>8</sup> These values are not based upon scientific and validated data, and the study was not designed to determine these contamination levels. The results of the current study suggest that there is no reason to replace microbiological sampling with particle counting for routine evaluation of microbiological contamination in conventionally ventilated operating theatres. This relationship should be evaluated in other high-risk, filtered air areas in hospitals.

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# **EXHIBIT DX54**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS

# Predicting bacterial populations based on airborne particulates: A study performed in nonlaminar flow operating rooms during joint arthroplasty surgery

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**Background:** Prevention of postsurgical infection is preferable to treatment. Prevention requires identification and control of the potential sources of microbial contamination. This study investigated whether the density of airborne particulates can predict the density of viable airborne bacteria at the surgery site.

**Methods:** A standard particle analyzer was used to measure the number and diameter of airborne particulates during 22 joint arthroplasty surgeries. An impact air sampler and standard culture plates were used to identify and count colony-forming units (CFU).

**Results:** Particulate density averaged  $>500,000$  particles/m<sup>3</sup> per 10-minute interval, and 1786 CFU were identified, primarily gram-positive cocci. A particle density  $\geq 10$   $\mu$ m explained 41% of the variation in CFU density. Particle and CFU density increased with longer surgery duration and higher staff counts.

**Conclusions:** These findings support the use of environmental controls that isolate and protect the surgical site from airborne particulates and contamination.

**Key Words:** Surgical; nosocomial; airborne.

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Current estimates indicate that infection occurs in 0.5% to 11% of surgeries, affecting the lives of thousands of patients each year.<sup>1,2</sup> Prevention of infection is preferable to treatment in terms of both patient outcomes and cost of treatment.<sup>3,4</sup> Prevention requires identification and control of the potential sources of microbial contamination.

One potential source of contamination is the air inside the operating room. Studies have demonstrated a correlation between airborne bacterial contamination and postoperative joint sepsis in joint arthroplasty surgery.<sup>5-7</sup> Other studies have addressed the potential for airborne bacteria to result in bacterial deposition in surgical wounds.<sup>8-12</sup> Data on the presence of airborne

microbes in the operating room environment, particularly at the surgery site, can be relevant in predicting the risk of infection.

While measuring airborne bacteria during surgical procedures is not currently feasible, measuring the particulates in the air is relatively simple. Because bacteria compose a portion of the total airborne particulate mass, airborne particulate counts can be correlated with airborne microbial density. The literature regarding the relationship between airborne particulates and airborne microbes is unclear, however; for example, Landrin et al<sup>13</sup> reported no correlation between particle and bacteria counts in operating rooms, but Seal and Clark<sup>14</sup> found a correlation. The study of Landrin et al was conducted in an empty operating room, which does not represent the movements of equipment, operating room staff, and patient typically occurring during orthopedic surgery. The Seal and Clark study data were collected from only 2 actual surgical procedures, calling into question the generality of their results.

The purpose of this study was to determine whether the density of airborne particulates at the surgery site and various behaviors of operating room personnel can be used to predict the density of viable airborne bacteria (ie, colony-forming units [CFU]) at the surgery site during hip and knee joint arthroplasty.

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## MATERIALS AND METHODS

Approval from the institutional review board at the study institution was obtained before study initiation. Twenty-two patients (10 women, 12 men; mean age  $60.0 \pm 12.8$  years) who had consented to undergo primary hip arthroplasty (6 total and 7 resurfacing) or knee arthroplasty (8 total and 1 unicompartmental) were recruited to participate in this study. Four surgical procedures were chosen that varied with respect to instrumentation, surgical staff, and operating room traffic (eg, for portable radiography during hip procedures), to ensure variability in these factors, which have been identified as possibly related to particulate and CFU counts. Potential subjects were given a written explanation of the study and volunteered to participate by signing an informed consent. Demographic information (age, sex, height, weight, hip vs knee surgery, and comorbidities) was collected for each subject. The surgical procedures were performed between July 1, 2007 and September 19, 2007. All patients received prophylactic intravenous (IV) antibiotics before any skin incisions.

### Environment

All air sampling was done during hip arthroplasty and knee arthroplasty procedures performed in 2 operating rooms at the study institution. These are nonlaminar air flow rooms with a conventional ventilation system (turbulent air flow) with a minimum of 15 exchanges per hour. Air passes through a prefilter and a Varicell filter (95% effective at removing particles  $\geq 0.3 \mu\text{m}$ ) before being diffused into the room through ceiling vents. Air temperature and humidity are controlled by conventional HVAC methods at set points and approximate ranges of  $16^\circ\text{C} \pm 1^\circ\text{C}$  and  $50\% \pm 7\%$  relative humidity. The operating rooms were kept at a positive pressure level of 0.20-inch water gauge compared with the outer hall and 0.15-inch water gauge relative to the central supply area, to prevent the intrusion of airborne contaminants into the rooms.

The surgeon (G.W.S.) and first assistant (B.T.) wore filtered exhaust helmets and suits during all surgeries. In one operating room, scrub technicians also wore filtered exhaust helmets and suits, but in the other operating room, they did not. Surgical personnel working in the operating room outside the sterile surgical field (eg, circulating nurses, anesthesiologists, radiology technicians, other technicians) wore standard cotton surgical scrub shirts and pants, surgical masks, and hair coverings. These environmental conditions were routine for hip and knee arthroplasty cases performed by this surgeon.

Both operating rooms had 2 entry points via self-closing doors; one door opened to an outer hall, and

the other door opened into a central sterile supply area. Access to the sterile supply area was restricted to personnel wearing scrubs, face masks, and hair and shoe covers. The door to the outer hall was locked during surgery to prevent unnecessary traffic, although the door was opened to allow the entrance of radiology equipment.

At the beginning of each 10-minute interval, the number of persons in the room (staff count) was documented, and all entries and exits over the course of the 10-minute interval (traffic flow) were recorded. The duration of the surgical procedure was recorded, as was the specific operating room in which the surgery was performed.

### Particulate counts

Airborne particulates were measured using a standard particle analyzer (LASAIR II 310B; Particle Measuring Systems, Boulder, CO) that had been calibrated in May 2007. The particle analyzer sampled continuously throughout the surgical procedure at a rate of  $0.0283 \text{ m}^3/\text{min}$  ( $1.0 \text{ ft}^3/\text{min}$ ) and logged data at 1-minute intervals to obtain sample volumes of  $0.0283 \text{ m}^3$  (28.3 L) of air. The samples were collected through a 100-cm length of sterile Bev-a-line (Thermoplastic Processes, Stirling, NJ) or PVC tubing. The end of the sterile tubing was placed inside the surgical field at a standard location on the "overhead" mayo stand, approximately 40 cm from the surgical wound during hip arthroplasty. Air was drawn through the tube and into the analyzer, where it crossed a laser field. Interruption of the laser field by the particles was detected by an electronic sensor that produced an automated count of the passing particles and measured the diameter of each particle. Particles were classified by diameter (d) in 6 size ranges:  $0.3 \leq d < 0.5 \mu\text{m}$ ,  $0.5 \leq d < 1.0 \mu\text{m}$ ,  $1.0 \leq d < 3.0 \mu\text{m}$ ,  $3.0 \leq d < 5.0 \mu\text{m}$ ,  $5.0 \leq d < 10.0 \mu\text{m}$ , and  $d \geq 10 \mu\text{m}$ . The count and particle size measures were continuously recorded electronically by the particle analyzer. This information was partitioned into blocks of volume and time that were consistent with the bacterial counting method. Positive hole correction was carried out using tables for 400-hole impactors.

### Viable bacteria counts

Airborne viable bacteria counts were measured using an impact air sampler (Anderson N6; Environmental Monitoring Systems, Charlotte, SC). The impact air sampler sampled air at the same rate as the particle analyzer, using a similar collection method and PVC tubing. The sampling end of the tubing was placed adjacent to the particle counter air sampling tube within the sterile surgical field. Air drawn through the tube was passed to a standard culture plate containing

tryptic soy agar with 5% sheep's blood (Healthlink, Jacksonville, FL). Particulate, which included any viable bacteria, collected on the agar surface. The plates were exchanged every 10 minutes throughout the surgical procedure; the exchanging process took approximately 20 seconds. The plates were incubated at 35°C for 3 days. Gram staining and morphological identification were used to identify and count viable bacteria. Viable bacteria were reported as CFU/m<sup>3</sup>, a standard unit of measurement for viable bacterial counts. Control plates were handled in the same manner as the test plates, but without exposing them during the surgery. The control plates were used to determine whether handling of the plates contributed to microbial contamination.

### Data analysis

Descriptive statistics and data plots were used to evaluate the distributions of the variables. Because the distribution for CFU/m<sup>3</sup> was highly skewed, a square root transformation ( $\sqrt{\text{CFU/m}^3}$ ) was used to approximate the normal distribution assumed by the linear model. Multilevel (random coefficient) regression analyses were used to analyze the data; this type of analysis is appropriate for longitudinal data with different numbers of data points for each case and inclusion of time-varying covariates (eg, staff count and traffic flow in each 10-minute interval).<sup>15,16</sup> The regression model compared the variation in  $\sqrt{\text{CFU/m}^3}$  within each 10-minute measurement interval to the variations in the predictor variables at each measurement interval while accounting for the dependencies in the data due to the clustering of measurements within surgical cases.

The potential predictors of  $\sqrt{\text{CFU/m}^3}$  included duration of surgery, total particulate count/m<sup>3</sup>, the particulate counts in each diameter category, staff count, and traffic flow. The relations between  $\sqrt{\text{CFU/m}^3}$  and each variable were evaluated in separate analyses. A multivariate model was developed to predict  $\sqrt{\text{CFU/m}^3}$ . The main effects of each included predictor variable and the respective interaction effects were tested. The models were evaluated by comparing the respective precisions of predicting  $\sqrt{\text{CFU/m}^3}$  (ie, comparing residual variance terms).

### RESULTS

We obtained data during 13 hip arthroplasty and 9 knee arthroplasty surgeries, yielding 147 10-minute intervals. Table 1 gives the averages and ranges for the variables included in this study. A total of 1786 CFU were grown in culture. The organisms cultured were 71% gram-positive cocci, 16% gram-positive bacilli, 6.3% gram-negative bacilli, and 7% other, several of

**Table 1.** Means and ranges for measures collected during 13 hip arthroplasty and 9 knee arthroplasty surgeries

Variable	Mean	Range
CFU/m <sup>3</sup> per 10-minute interval	12.5	0 to 93
Surgery duration, minutes	67	48 to 96
Particulate counts in 1000/m <sup>3</sup> per 10-minute interval		
Total (all diameters)	14,425	2972 to 43,311
Diameter 0.3 to 0.49 $\mu\text{m}$	12,708	2565 to 36,562
Diameter 0.5 to 0.99 $\mu\text{m}$	1333	216 to 7633
Diameter 1.0 to 2.9 $\mu\text{m}$	319	29 to 2174
Diameter 3.0 to 4.9 $\mu\text{m}$	39	4 to 243
Diameter 5.0 to 9.99 $\mu\text{m}$	23	2 to 122
Diameter $\geq 10 \mu\text{m}$	3	0 to 12
Staff count (average per 10-minute interval)	7.9	5 to 12
Traffic flow (operating room entries and exits per 10-minute interval)	5.6	0 to 18

**Table 2.** Statistical tests of the bivariate associations between each potential predictor variable and the  $\sqrt{\text{CFU/m}^3}$

Variable	Parameter estimate	t	P
Time	-0.016	-2.53	.016*
Particulate count in 1000/m <sup>3</sup>			
Total	<0.0001	1.22	.233
0.3 to 0.49 $\mu\text{m}$	<0.0001	1.21	.240
0.5 to 0.99 $\mu\text{m}$	0.0001	0.70	.484
1.0 to 2.9 $\mu\text{m}$	0.0004	0.75	.457
3.0 to 4.9 $\mu\text{m}$	0.0073	1.93	.056
5.0 to 9.99 $\mu\text{m}$	0.0156	2.46	.015*
$\geq 10 \mu\text{m}$	0.3232	4.65	<.001*
Staff count	0.31	2.62	.011*
Traffic flow	0.034	1.00	.319
Operating room	0.121	1.20	.246

NOTE. The parameter estimates in this table indicate the average change in  $\sqrt{\text{CFU/m}^3}$  per unit increase in the respective variable.

\*Statistically significant ( $P < .05$ ).

which have been associated with postoperative infections following hip and knee arthroplasty. None of the patients developed any clinical signs or symptoms of infection.

Table 2 shows the magnitudes of the relationships between each variable and  $\sqrt{\text{CFU/m}^3}$ . Neither sex ( $P = .267$ ) nor surgery type (ie, total hip arthroplasty, hip resurfacing, total knee arthroplasty, or unicompartmental knee arthroplasty;  $P = .093$ ) was significantly related to  $\sqrt{\text{CFU/m}^3}$ . Surgery duration, 5- $\mu\text{m}$  to 9.99- $\mu\text{m}$  particles/m<sup>3</sup>,  $\geq 10$ - $\mu\text{m}$  particles count/m<sup>3</sup>, and staff count were each significantly ( $P < .05$ ) related to  $\sqrt{\text{CFU/m}^3}$ .

The regression model including the number of 10- $\mu\text{m}$  particles/m<sup>3</sup> as the only predictor was determined to be the final model predicting  $\sqrt{\text{CFU/m}^3}$

**Table 3.** Comparison of multivariable models to predict  $\sqrt{\text{CFU/m}^3}$ 

Model and variables	Parameter estimate	t	P	SEE (CFU/m <sup>3</sup> )
Model 1				$\pm 8.7$
Time	-0.10	-1.17	.254	
5.0 to 9.99 $\mu\text{m}$	0.011	1.42	.159	
Model 2				$\pm 8.4$
Time	-0.03	-0.35	.727	
$\geq 10 \mu\text{m}$	0.318	4.13	<.001*	
Model 3				$\pm 8.4$
$\geq 10 \mu\text{m}$	0.297	4.26	<.001*	
Staff count	0.216	1.88	.064	
Model 4				$\pm 8.3$
5.0 to 9.99 $\mu\text{m}$	-0.039	-3.25	.001*	
$\geq 10 \mu\text{m}$	0.742	5.15	<.001*	
Model 5				$\pm 8.4$
$\geq 10 \mu\text{m}$	0.325	4.65	<.001*	

NOTE. Particulate counts are in 1000/m<sup>3</sup>. Parameter estimate refers to the average increase in  $\sqrt{\text{CFU/m}^3}$  per unit increase in the variable while controlling for the values of the other variables in the respective model.

SEE, standard error of estimation.

\*Statistically significant ( $P < .05$ ).

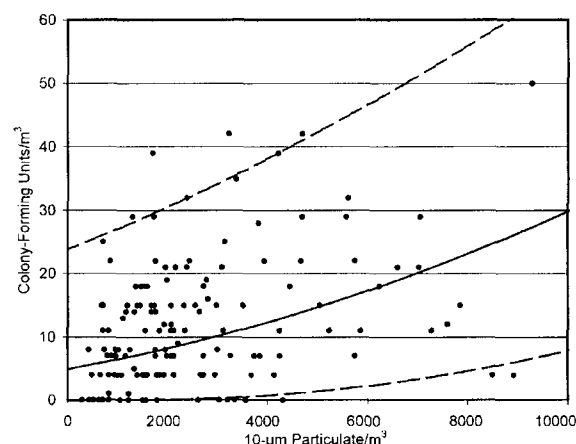
in these data. The 10- $\mu\text{m}$  particles/m<sup>3</sup> accounted for approximately 41% of the observed variation in CFU/m<sup>3</sup> between surgery cases. On average, at least 1 additional CFU/m<sup>3</sup> was detected for every 700 10- $\mu\text{m}$  particles/m<sup>3</sup>. None of the other tested models improved prediction accuracy (Table 3).

The precision of predicting CFU/m<sup>3</sup> counts from particulate count was limited. The 95% prediction interval for CFU/m<sup>3</sup> count (ie, after back-transformation of  $\sqrt{\text{CFU/m}^3}$ ) ranged from  $\pm 12$  CFU/m<sup>3</sup> at low (<2000) 10- $\mu\text{m}$  particles/m<sup>3</sup> to  $\pm 32$  CFU/m<sup>3</sup> at high (>8000) 10- $\mu\text{m}$  particles/m<sup>3</sup> (Fig 1).

Table 2 shows that surgery duration and staff count appear to be related to  $\sqrt{\text{CFU/m}^3}$ , but these variables were not statistically significant in any of the tested models (Table 3). Follow-up analyses revealed that both surgery duration ( $P < .001$ ) and staff count ( $P = .036$ ) were significantly correlated with the number of 10- $\mu\text{m}$  particles/m<sup>3</sup>. Longer surgery duration and higher staff counts were thus associated with both higher  $\sqrt{\text{CFU/m}^3}$  and higher 10- $\mu\text{m}$  particles/m<sup>3</sup>. Consequently, the addition of these variables as predictors in addition to 10- $\mu\text{m}$  particles/m<sup>3</sup> failed to improve the prediction accuracy for  $\sqrt{\text{CFU/m}^3}$ .

## DISCUSSION

The number of 10- $\mu\text{m}$  particles/m<sup>3</sup> and the number of surgical staff in the operating room were associated with the CFU/m<sup>3</sup> at the surgical site during hip and knee joint arthroplasty. The number of surgical staff was correlated with the number of 10- $\mu\text{m}$  particles/m<sup>3</sup>. Thus, after controlling for 10- $\mu\text{m}$  particles/m<sup>3</sup>, the number of surgical



**Fig 1.** CFU count as a function of 10- $\mu\text{m}$  particulate count. The solid line shows the model-predicted CFU/m<sup>3</sup> using 10- $\mu\text{m}$  particles/m<sup>3</sup>. The dashed lines show the 95% prediction interval.

staff was not related to CFU/m<sup>3</sup>. A logical interpretation of these data is that increasing surgical staff produces more particulates and more CFUs. Consequently, limiting surgical staff to essential personnel may be a way to control the density of airborne particulates and CFUs in the operating room.

The finding of a correlation between the number of 10- $\mu\text{m}$  particles/m<sup>3</sup> and CFU/m<sup>3</sup> at the surgical site has several important implications. First, it supports airborne particulate contamination of the wound as a source of postoperative infection in joint arthroplasty, as emphasized by Edmiston et al.<sup>17</sup> Second, it lends support to the use of environmental controls in the operating room to limit the number of airborne microbes, such as laminar flow, ultraviolet light, and body-exhaust hoods<sup>18-24</sup> (although it should be noted that a few recent articles have reported that the use of laminar air flow has no apparent effect on postoperative infection rates<sup>25,26</sup>). Third, it suggests that monitoring particulate counts during joint arthroplasty possibly could provide a real-time proxy for increased risk of wound contamination or infection.

We also found a relationship between the number of persons present in the operating room and the CFU/m<sup>3</sup> at the surgery site. This finding is consistent with several previous studies indicating that the source of airborne contaminants in the operating room is surgical and support staff.<sup>18-23</sup> Using bacterial "fingerprinting," one study traced the actual infectious organism in postoperative wound infections to specific members of the operating team.<sup>17</sup> Because the number and behavior of staff present at the surgery table remained relatively constant throughout the study, the activity of persons

in the periphery of the operating room appeared to have contributed to the presence of CFU inside the sterile field at the surgery site. The mean number of personnel in the operating room in each 10-minute interval was 7.9 people (range, 5 to 12). This included a research assistant in addition to the surgeon, first assistant, scrub technician, anesthesiologist (or CRNA) and circulating nurse. One or more sales representatives from implant companies often were present. One or 2 radiology technicians entered and exited the room for portable radiographs during hip arthroplasty. Sometimes a surgical resident, surgical tech student, or additional nurses were present as well. This number of personnel seems high, considering the "limited access" status of the surgical suite. Because particulates and perhaps CFUs may be originating from the peripheral personnel in the operating room, practices that minimize the number of personnel present during surgery may be warranted.

There is no universally recognized standard for acceptable or safe CFU density during surgery. A generally accepted level of airborne microbes for joint arthroplasty is 10 CFU/m<sup>3</sup> in the region of the surgical field.<sup>5,18</sup> In our study of turbulent air flow operating rooms, we measured a mean of 12.5 CFU/m<sup>3</sup> at the surgery site per 10-minute sampling interval. However, a relatively high degree of intraoperative variance existed, with densities ranging from 0 to 93 CFU/m<sup>3</sup>. When the density of 10- $\mu$ m particles in these operating rooms exceeded 3000 particles/m<sup>3</sup> in any 10-minute interval, the average CFU count at the surgical site exceeded 10 CFU/m<sup>3</sup> during that interval.

This relationship between the density of airborne particulate and the presence of viable microorganisms supports the notion that an airborne particle counter may serve as a real-time proxy for airborne bacterial contamination during surgery. Standard practice for detecting and quantifying airborne microorganisms in an operating room is to collect organisms on agar plates using sedimentation or slit sampling methods. The plates are incubated, and CFUs are counted. This method has several disadvantages: (1) It typically takes 3 to 5 days to obtain the results; (2) agar plates typically collect a sample that is remote from the surgical site; and (3) it would be impractical and cost-prohibitive to conduct such monitoring routinely. Commercially available airborne particle counters are portable and provide immediate data on airborne particulate densities, which we observed to be associated with CFU counts at the surgical site. Further studies are needed to validate the use of particulate density to predict the density of airborne microbes.

While our study found a correlation between the number of people in the operating room and the CFUs at the surgical site, no relationship with traffic

flow (ie, the number of entrances and exits) was detected. The relationship between CFUs and number of personnel in the OR has been reported by several previous studies.<sup>23,27-30</sup> Some of these studies also have found that traffic flow is related to CFUs. Traffic flow may not have been significant in our study due in part to the relatively high positive pressure in the operating rooms relative to adjacent hallways. The operating rooms had a minimum positive pressure of 0.15 inches of water. The Centers for Disease Control and Prevention recommend at least 0.03-inch water-gauge positive pressure difference between the operating room and adjoining areas.<sup>31</sup> The differential at our facility exceeds this recommendation by several fold, which may have limited the effects of personnel ingress and egress on airborne particulate.

Bacteria are generally  $\geq 1 \mu\text{m}$  in size and have a tendency to cluster together and attach to other larger particles. Airborne bacteria-carrying particles measure 4  $\mu\text{m}$  to 20  $\mu\text{m}$ .<sup>32</sup> It is likely that the correlation of larger particles ( $> 5 \mu\text{m}$ ) with CFUs observed in our study was attributable to the capability of larger particles to carry bacteria. Smaller particles are present in much higher numbers than larger ones, so monitoring particles without discriminating for size ranges obscures identification of the larger particles that may be carrying microbes. This may explain why some previous studies failed to detect a correlation between number of particles and CFUs.

We found that the number airborne particles  $\geq 10 \mu\text{m}$  was correlated with the number of CFUs grown from air sampled within the sterile field approximately 40 cm from the surgical incision. The number of 10- $\mu\text{m}$  particles was associated with the number of staff members present in the operating room during surgery. These observations support the use of environmental controls that isolate and protect the surgical site from airborne particulates and contamination.

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# **EXHIBIT DX55**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS

# Can Particulate Air Sampling Predict Microbial Load in Operating Theatres for Arthroplasty?

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## Abstract

Several studies have proposed that the microbiological quality of the air in operating theatres be indirectly evaluated by means of particle counting, a technique derived from industrial clean-room technology standards, using airborne particle concentration as an index of microbial contamination. However, the relationship between particle counting and microbiological sampling has rarely been evaluated and demonstrated in operating theatres. The aim of the present study was to determine whether particle counting could predict microbiological contamination of the air in an operating theatre during 95 surgical arthroplasty procedures. This investigation was carried out over a period of three months in 2010 in an orthopedic operating theatre devoted exclusively to prosthetic surgery. During each procedure, the bacterial contamination of the air was determined by means of active sampling; at the same time, airborne particulate contamination was assessed throughout the entire procedure. On considering the total number of surgical operations, the mean value of the total bacterial load in the center of the operating theatre proved to be 35 CFU/m<sup>3</sup>; the mean particle count was 4,194,569 no./m<sup>3</sup> for particles of diameter  $\geq 0.5 \mu\text{m}$  and 13,519 no./m<sup>3</sup> for particles of diameter  $\geq 5 \mu\text{m}$ . No significant differences emerged between the median values of the airborne microbial load recorded during the two types of procedure monitored. Particulates with a diameter of  $\geq 0.5 \mu\text{m}$  were detected in statistically higher concentrations ( $p < 0.001$ ) during knee-replacement procedures. By contrast, particulates with a diameter of  $\geq 5 \mu\text{m}$  displayed a statistically higher concentration during hip-replacement procedures ( $p < 0.05$ ). The results did not reveal any statistically significant correlation between microbial loads and particle counts for either of the particle diameters considered ( $\geq 0.5 \mu\text{m}$  and  $\geq 5 \mu\text{m}$ ). Consequently, microbiological monitoring remains the most suitable method of evaluating the quality of air in operating theatres.

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## Introduction

All surgical procedures carry a risk of post-operative infection, which can be particularly serious in orthopedic surgery such as joint replacement [1]. The prevention of surgical site infection (SSI) after orthopedic implant surgery is a hot topic for politicians, hospital administrators and clinicians, given the enormous amount of resources these infections consume in terms of extra costs of medications, reoperations, and prolonged hospitalization [2]. Prevention involves identifying and controlling potential sources of microbial contamination.

Factors causing surgical site infections are multivarious [3], including surgical characteristics (e.g. type of procedure, duration of the operation etc), the appropriateness of staff behaviors (limited number of personnel and restricted movements) and microbial contamination of the air (especially in clean surgery) [4], [5]. In turn, the latter factor can be, at least partially, determined by factors linked to the surgical characteristics and staff behaviors.

Several studies have proposed that the microbiological quality of the air in operating theatres be indirectly evaluated by means of particle counting, a technique derived from industrial clean-room technology standards [6], using airborne particle concentration as an index of microbial contamination [6], [7]. One of the sources of

airborne particulates in operating theatres may be the surgical smoke produced by particular instruments or techniques, such as the ultrasonic scalpel, electrocautery etc, during surgical procedures.

However, the relationship between particle counting and microbiological sampling has rarely been evaluated and demonstrated in operating theatres. Seal and Clark [8] compared airborne particle counting in eight size-ranges with the numbers of bacteria-carrying particles, in ultra-clean and turbulently ventilated operating theatres. They found that the number of particles in the 5–7  $\mu\text{m}$  size-range correlated significantly with microbiological contamination. Landrin et al [6] compared these two methods in empty operating theatres equipped with conventional ventilation through HEPA filters. No correlation was observed between the two methods (Spearman correlation coefficient = 0.06,  $P = 0.6$ ). These authors concluded that there was no reason to replace microbiological sampling with particle counting for the routine evaluation of microbiological contamination in conventionally ventilated operating theatres.

Another study that investigated whether the density of airborne particulates could predict the density of viable airborne bacteria was conducted by Stocks et al [9] during 22 arthroplasty procedures in operating rooms with a conventional ventilation

system (turbulent air flow). They found a correlation between the presence of larger particles ( $>5\ \mu\text{m}$ ) and microbial contamination, which was attributed to the capability of larger particles to carry bacteria. Thus, given the inhomogeneity of the results obtained, the literature regarding the relationship between airborne particulates and airborne microbes remains controversial.

The aim of the present study was to determine whether particle counting could predict microbiological contamination of the air in an operating theatre during 95 surgical arthroplasty procedures (hip and knee). In addition, we examined the possible correlations among the microbial load, particle counting and other variables: i.e. the frequency of use of instruments that generate particulates, door-opening rates, the number of persons present in the operating theatre and the duration of the surgical procedure.

## Methods

This investigation was carried out over a period of three months in 2010 in an orthopedic operating theatre devoted exclusively to prosthetic surgery and situated within a hospital facility in the north-west of Italy. About 1,200 hip- and knee-replacement procedures (ICD9-CM: 81.51–81.54) are performed per year in this operating theatre, which has a surface area of  $35.51\ \text{m}^2$  and is part of a complex that provides adequate space for reception, anesthesia, surgery, recovery and observation.

We monitored 95 surgical arthroplasty procedures: 59 hip replacements (ICD9-CM 81.51) and 36 knee replacements (ICD9-CM 81.54). During each procedure, the bacterial contamination of the air was determined by means of active sampling; at the same time, airborne particulate contamination was assessed throughout the entire procedure. Moreover, particle counts were recorded during the use of instruments able to produce surgical smoke.

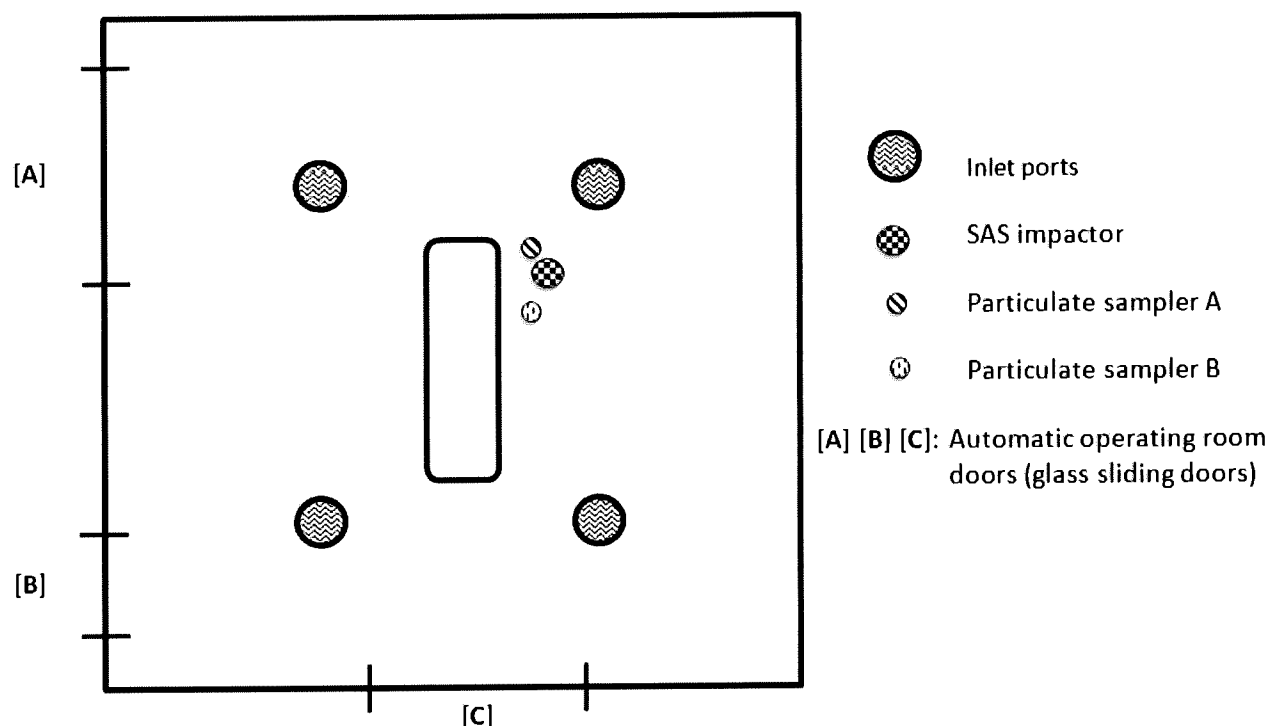
Figure 1 shows the floor plan of the operating theater and the positions of the air and particulate samplers.

During each operation, detailed information on the surgical procedure was collected, including the length of the procedure, the number of people present in the theatre, the door-opening rate per procedure, and the duration of use of instruments that produce surgical smoke.

At the beginning of the study, when the operating theatre was at rest, we recorded the number of air exchanges provided by the air-conditioning system and checked for any microbial contamination of the airflow from the inlet ports of the system. The operating theatre has a turbulent-flow ventilation system equipped with HEPA filters, which are 99.97% efficient in removing airborne particles of  $0.3\ \mu\text{m}$  or larger; the filters are replaced every 6 months and maintenance work on the system is carried out periodically. The operating room is under positive pressure in relation to the adjacent rooms ( $\geq 5\ \text{Pa}$ ); air temperature and humidity are set respectively at  $17^\circ\text{C} \pm 1^\circ\text{C}$  and  $50\% \pm 5\%$ .

## Determining Bacterial Contamination of the Air from the Inlet Ports and in the Centre of the Room

To determine the total airborne bacterial load, we used an SAS SUPER 100 (PBI International®) impactor equipped with RODAC plates ( $\varnothing = 55\ \text{mm}$ ) containing  $\gamma$ -irradiated TSA (Tryptone Soy Agar) culture medium (Biotest Italia s.r.l.). In order to sample the air in the centre of the room, the instrument was positioned in the immediate vicinity of the operating table, at a height of 1.5 m. During each procedure, a 1000 L volume of air was aspirated by means of a multi-aspiration modality; the impactor was switched on by remote control just as the skin was incised, and was switched off on completion of suturing.



**Figure 1. Floor plan of the operating theater, showing the positions of the samplers.**

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To determine the bacterial load of the airflow from the inlet ports of the ventilation system in at-rest conditions, the sampler was positioned in proximity to the flow-regulators. The total volume of air sampled was 1000 L.

Plates were incubated at 37°C for 48 h before the total aerobic bacterial count was measured. Microbiological results are expressed as CFU (Colony Forming Units)/m<sup>3</sup>.

### Determining Contamination by Airborne Particulates

Airborne particulates (particles  $\geq 0.5 \mu\text{m}$  and particles  $\geq 5 \mu\text{m}$  in size) were counted by means of two light-scattering particle analyzers (Met One, Pacific Scientific Instruments, Grants Pass, OR, USA) at a flow rate of 2.8 L/min., and expressed as numbers of particles per m<sup>3</sup>. Both apparatuses were placed in the same position as the SAS impactor; one (Sampler A) was activated by remote control in parallel with the impactor, i.e. for the entire duration of the procedure, while the other (Sampler B), again activated by remote control, recorded the particle count both on each occasion when surgical smoke-producing instruments were used and when such instruments were not used.

### Determining the Number of Efficacious Air Exchanges

The efficacy of the air-conditioning system was assessed in at-rest conditions by measuring the decay of the concentration of tracer gas by means of a portable GA301 meter (Eco-CONTROL, Milan) connected to a computer for the collection and analysis of data, as described by Sartini et al [10].

### Statistical Analysis

Statistical analysis was carried out by means of STATA SE9™ software (Stata Corp LP - USA). The results were analyzed in terms of descriptive statistics, and the relationships between data were examined by using the non-parametric Mann-Whitney-Wilcoxon ranksum test. The rho Spearman rank correlation was used to assess the degree of association among particulate diameter  $\geq 5 \mu\text{m}$ , particulate diameter  $\geq 0.5 \mu\text{m}$ , bacterial load, procedure duration, percentage frequency of ultrasonic scalpel use, number of persons present and door-opening rate.

Moreover, the sensitivity and specificity of particle counting in discriminating between microbiological counting values were evaluated by means of receiver-operating characteristic (ROC) analysis.

### Ethics Statement

We didn't need ethics approval because the study was carried out as part of routine control tests that we conduct in the operating theatres of the Hospital. As is the case of all studies conducted in the hospital environment, the General Management of the hospital approved the study protocol. The General Management is responsible for ensuring the ethical aspects of all activities of the hospital. Furthermore, the entire study was organised in accordance with a protocol agreed upon with the operating theatre teams. On entering the hospital, all patients sign an informed consent form regarding treatments in the hospital and the conditions of those treatments. Finally, the research was carried out in full respect of the Italian law on the privacy (Decreto legislativo 30 giugno 2003, n. 196).

### Results

With regard to the characteristics of the air-conditioning system, 20 efficacious air exchanges were carried out per hour. The microbial load of the airflow through the inlet ports proved to be  $<1 \text{ CFU/m}^3$ .

On considering the total number of surgical operations, the mean value of the total bacterial load in the center of the operating theatre proved to be  $35 \text{ CFU/m}^3$ ; the mean particle count measured by Sampler A was  $4,194,569 \text{ no./m}^3$  for particles of diameter  $\geq 0.5 \mu\text{m}$  and  $13,519 \text{ no./m}^3$  for particles of diameter  $\geq 5 \mu\text{m}$  (Table 1).

Table 1 also reports the data on the microbial load and on the counts of particles of the 2 diameters ( $\geq 0.5$  and  $\geq 5 \mu\text{m}$ ), subdivided by type of procedure. No significant differences emerged between the median values of the airborne microbial load (hip replacement median value:  $35 \text{ CFU/m}^3$ ; knee replacement median value:  $40 \text{ CFU/m}^3$ ) recorded during the two types of procedure monitored ( $p=0.4558$ ).

Particulates with a diameter of  $\geq 0.5 \mu\text{m}$  were detected in statistically higher concentrations ( $z=-6.013$ ;  $p=0.0000$ ) during knee-replacement procedures (median value  $6,468,327 \text{ no./m}^3$ ). By contrast, particulates with a diameter of  $\geq 5 \mu\text{m}$  displayed a statistically higher concentration ( $z=2.013$ ,  $p=0.0441$ ) during hip-replacement procedures (median value  $14,520 \text{ no./m}^3$ ).

Table 2 reports the data on the duration of the procedures, the number of persons present in the room and door-opening rates. The difference in the median duration of the two types of procedure (hip-replacement: 40 min; knee-replacement: 45 min) proved to be statistically significant ( $z=-3.569$ ;  $p=0.0004$ ).

**Table 1.** Mean values, standard deviations (SD), minimum and maximum values, median and quartiles (Q1–Q3) of the total bacterial load (CFU/m<sup>3</sup>) and counts of particles (Sampler A) of diameter  $\geq 0.5 \mu\text{m}$  and diameter  $\geq 5 \mu\text{m}$  (no./m<sup>3</sup>) in all the procedures monitored and in each of the two types of procedure.

Total airborne bacterial load (CFU/m <sup>3</sup> )			
	Hip replacement	Knee replacement	All procedures
Mean $\pm$ SD	35 $\pm$ 16	34 $\pm$ 11	35 $\pm$ 15
Min-max	10–70	20–45	10–70
Median	35	40	40
Q1–Q3	25–40	22–45	25–45
Count of airborne particles of diameter $\geq 0.5 \mu\text{m}$ (no./m <sup>3</sup> )			
	Hip replacement	Knee replacement	All procedures
Mean $\pm$ SD	2,538,425 $\pm$ 1,480,054	6,908,804 $\pm$ 3,269,100	4,194,569 $\pm$ 3,142,263
Min-max	600,353–5,164,279	2,925,281–11,219,627	600,353–11,219,627
Median	2,418,086	6,468,327	3,127,466
Q1–Q3	1,294,603–3,586,316	3,760,520–9,683,440	1,630,903–5,164,279
Count of airborne particles of diameter $\geq 5 \mu\text{m}$ (no./m <sup>3</sup> )			
	Hip replacement	Knee replacement	All procedures
Mean $\pm$ SD	13,915 $\pm$ 3,592	12,868 $\pm$ 3,488	13,519 $\pm$ 3,571
Min-max	5,879–19,756	8,352–17,764	5,879–19,756
Median	14,520	12,207	14,520
Q1–Q3	12,657–16,608	9,926–16,046	11,500–16,608

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**Table 2.** Mean, standard deviation (SD), median and range of the values of procedure length (min), number of persons present in theatre, and door-opening rate (no./min) for all surgical procedures and for hip and knee replacements.

All surgical procedures		
	Mean $\pm$ SD	Median (range)
Operation length (min)	45 $\pm$ 10	40 (35–70)
N° persons present	8 $\pm$ 1	7 (6–10)
Door-opening rate (no./min)	0.20 $\pm$ 0.03	0.20 (0.12–0.26)
Hip replacement (ICD9-CM 81.51)		
Operation length (min)	41 $\pm$ 6	40 (35–50)
N° persons present	8 $\pm$ 1	8 (6–10)
Door-opening rate (no./min)	0.20 $\pm$ 0.03	0.20 (0.12–0.26)
Knee replacement (ICD9-CM 81.54)		
Operation length (min)	50 $\pm$ 12	45 (40–70)
N° persons present	6 $\pm$ 1	6 (6–7)
Door-opening rate (no./min)	0.20 $\pm$ 0.04	0.18 (0.16–0.25)

doi:10.1371/journal.pone.0052809.t002

During each operation, doors were opened a mean of 0.20 times per minute, with no statistically significant difference emerging between the two types of procedure ( $p = 0.2334$ ).

All operating theatre staff wore nonwoven fabric suits; surgeons also wore highly effective isolation helmets, and instrument-handlers wore semi-integral masks, while the anesthetist and circulating nurses wore surgical masks and hair covering.

Evaluation of the surgical instruments able to release surgical smoke revealed that the ultrasonic scalpel was the instrument most frequently used in both types of procedure. Figure 2 reports the duration of the use of the ultrasonic scalpel as a percentage of procedure time (calculated as minutes of use/procedure duration  $\times$  100), subdivided by type of procedure. In this regard, statistically significant differences ( $z = -3.145$ ;  $p = 0.0017$ ) emerged between the two types of procedure.

Airborne particulate concentration as a function of the use of the ultrasonic scalpel was evaluated by means of Sampler B. This evaluation revealed that the median concentration of particulates with a diameter of  $\geq 0.5 \mu\text{m}$  was significantly higher ( $z = -4.432$ ;  $p = 0.000$ ) when this instrument was used (8,014,873 no./ $\text{m}^3$ ) than when it was not used (2,958,536 no./ $\text{m}^3$ ). A similar pattern was seen in the concentration of  $\geq 5 \mu\text{m}$  diameter particles (13,965 no./ $\text{m}^3$  vs. 12,878 no./ $\text{m}^3$ ), though the difference was not statistically significant ( $p = 0.2019$ ).

A highly significant correlation emerged between the percentage use of the ultrasonic scalpel and the duration of the procedures ( $\rho = 0.8254$   $p < 0.001$ ). Table 3 reports of the Spearman correlation coefficients ( $\rho$ ) and significances ( $p$ ) of the mean concentrations of particulates ( $\geq 0.5 \mu\text{m}$  and  $\geq 5 \mu\text{m}$ ) recorded by Sampler A in relation to procedure duration (min), percentage use of the ultrasonic scalpel, number of persons present and door-opening rate, both for the total number of procedures and for each procedure type (hip and knee replacement).

The results did not reveal any statistically significant correlation between microbial loads and particle counts for either of the particle diameters considered ( $\geq 0.5 \mu\text{m}$  and  $\geq 5 \mu\text{m}$ ).

A statistically significant correlation ( $\rho = 0.2344$   $p < 0.05$ ) emerged between the number of persons present in the operating theatre and the airborne microbial load during both types of procedure.

On the basis of ROC analysis, no particulate count value for the diameters of  $\geq 0.5$  and  $\geq 5 \mu\text{m}$  can predict a microbiological count higher than 20 CFU/ $\text{m}^3$  (ROC area = 0.4661 and 0.1080, respectively). The choice of this cut-off was determined by the fact that the national standard reference value for operating theatres with turbulent-flow ventilation (180 CFU/ $\text{m}^3$ ) has never been reached; the most suitable cut-off value for our data proved to be the Italian and British standard value indicated for operating theatres in which ultraclean surgery is performed, despite the fact that laminar-flow ventilation is recommended.

## Discussion

During surgical procedures, dust particles, textile fibers, skin scales and respiratory aerosols loaded with viable microorganisms are released from the surgical team and patient into the surrounding air of the operating room [11]. Moreover, the use of some particular instruments during surgical procedures increases the dispersion of particulates in the air. The size of such particles closely depends on the particular instruments used. Indeed, various investigations have revealed that the electrocautery releases the smallest particles, with a mean aerodynamic size of  $0.07 \mu\text{m}$ , whereas laser tissue coagulation produces larger particles ( $0.31 \mu\text{m}$ ) and the largest particles are generated by the ultrasonic scalpel ( $0.35$ – $6.5 \mu\text{m}$ ) [12].

The aim of the present study was to determine whether the concentration of the airborne particulates could predict microbial contamination during surgical operations. Particle counting could offer several advantages over microbiological sampling. Indeed, microbiological sampling is time-consuming and the results may only be available after several days [6]. Another critical point concerning microbiological sampling is the absence of uniform standardized sampling procedures, which prevents data collected in different countries from being compared. In addition, a range of instruments are used in volumetric air-sampling, which hampers the correlation of results on account of their variability [3].

Conversely, particle counting is less demanding and yields immediate results. However, the information obtained is indirect [6]. This method enables results to be compared with reference values applicable to classes of maximum particle concentration. Most industrialized countries have set their own standards, based on measuring the presence of particles of varying sizes and number; many of these standards have been amended to conform to the International Standards Organization (ISO) 14644 [3], [13].

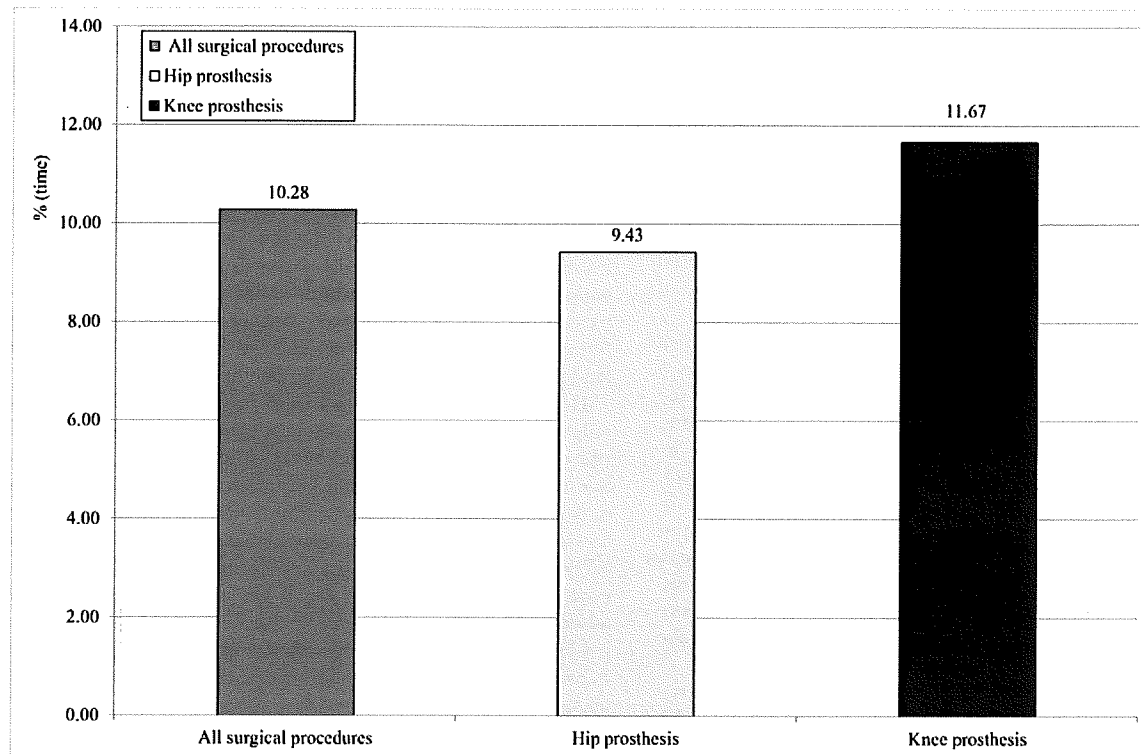
Some similar studies [6], [8], [9] have yielded results which conflict with one another, thus leaving the question unresolved.

With regard to microbial contamination in operating theatres, it is well known that the number of airborne bacteria depends on several factors, such as the number of people present in the room and their activities and behavior.

Few countries have set bacterial threshold limits in conventionally-ventilated operating theatres, although most recommend 20 air exchanges per hour, so as not to exceed values of 50–150 colony forming units (CFU)/ $\text{m}^3$  of air during surgical operations.

In some countries, the concentration should not exceed 180 CFU/ $\text{m}^3$  for an average 5-min period during activity [3].

In France [14], the microbiological limits are more restrictive than in Italy [15] and the UK, with values of  $\leq 20$  CFU/ $\text{m}^3$  and  $\leq 5$  CFU/ $\text{m}^3$  being indicated for turbulent and unidirectional airflows, respectively [16].



**Figure 2. Duration of use of the ultrasonic scalpel as a percentage of operating time, subdivided by type of procedure.**  
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In the present study, the mean values of the airborne microbial load ( $35 \text{ CFU/m}^3$ ) proved to be below the standard values for conventionally-ventilated [15] operating theatres in Italy. However, they exceeded the values proposed in some countries, such as France, and the generally accepted level of airborne microbial

contamination during arthroplasty ( $10 \text{ CFU/m}^3$ ) [10]. The values that we recorded prove to be higher than those reported in other studies of the same types of surgical procedure [9], [17].

Our analysis of the quality of the air provided by the ventilation system revealed the microbial load of  $<1 \text{ CFU/m}^3$ ; it can

**Table 3. Spearman's correlation coefficients (Rho) and significances (p) between the mean concentration of particulate measured by Sampler A ( $\geq 5$  and  $\geq 0.5 \mu\text{m}$ ) and data on procedure duration (min), ultrasonic scalpel use, number of persons present in theatre and door-opening rates, referred to all procedures and broken down by procedure type (hip and knee replacement).**

	Mean concentration of particulate $\geq 5 \mu\text{m}$	Mean concentration of particulate $\geq 0.5 \mu\text{m}$
Procedure length (min) <sup>oo</sup>	$\rho = 0.1706$ ; $p = 0.0984$ (*)	$\rho = 0.6865$ ; $p < 0.001$ (*)
	$\rho = 0.2418$ ; $p = 0.0650$ (*)	$\rho = 0.1888$ ; $p = 0.1521$ (*)
	$\rho = 0.1343$ ; $p = 0.4350$ (§)	$\rho = 0.7622$ ; $p < 0.001$ (§)
% use of ultrasonic scalpel	$\rho = 0.1460$ ; $p = 0.1581$ (*)	$\rho = 0.7082$ ; $p < 0.001$ (*)
	$\rho = 0.2347$ ; $p = 0.0736$ (*)	$\rho = 0.8612$ ; $p < 0.001$ (*)
	$\rho = 0.5881$ ; $p < 0.001$ (§)	$\rho = 0.7933$ ; $p < 0.001$ (§)
N° persons present	$\rho = 0.2854$ ; $p < 0.01$ (*)	$\rho = 0.1624$ ; $p = 0.1158$ (*)
	$\rho = 0.4723$ ; $p < 0.001$ (*)	$\rho = 0.2104$ ; $p = 0.1097$ (*)
	$\rho = 0.3199$ ; $p = 0.0571$ (§)	$\rho = 0.1464$ ; $p = 0.3943$ (§)
Door-opening rate (no./min)	$\rho = 0.1184$ ; $p = 0.2530$ (*)	$\rho = 0.0378$ ; $p = 0.7159$ (*)
	$\rho = 0.2418$ ; $p = 0.0650$ (*)	$\rho = 0.0645$ ; $p = 0.6275$ (*)
	$\rho = 0.6895$ ; $p < 0.001$ (§)	$\rho = 0.1389$ ; $p = 0.4192$ (§)

<sup>oo</sup> skin - skin.

(\*) all procedures.

(\*) hip replacement.

(§) knee replacement.

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therefore be supposed that the contamination detected was produced during surgical activity.

With regard to particle counting, the results obtained revealed mean values that exceeded the European ISO 14644 Standard limits for ISO 7 clean-rooms ( $352 \times 10^3 \geq 0.5 \mu\text{m}$  particles/ $\text{m}^3$  and  $2,930 \geq 5 \mu\text{m}$  particles/ $\text{m}^3$ ) [13]. Moreover, the concentration values recorded in the present study, with regard to both sizes of particulates, differed from those reported by other similar studies conducted on conventionally ventilated operating theatres. However, it should be pointed out that these studies also differed considerably among themselves, again with regard to both sizes of particulates [9], [18].

It may reasonably be supposed that the utilization of surgical instruments that produce surgical smoke contributed to the high concentration of particulates. This supposition is supported by the fact that, with regard to particulates with a diameter of  $\geq 0.5 \mu\text{m}$ , we found a significantly higher concentration ( $p < 0.001$ ) when the ultrasonic scalpel was being used than when it was not. Moreover, a statistically significant correlation emerged between the percentage use of this instrument and the mean concentration of  $\geq 0.5 \mu\text{m}$  particles, and between procedure duration and the mean concentration of  $\geq 0.5 \mu\text{m}$  particles. On the basis of these findings, it may be hypothesized that, as the duration of the procedure increases, so also does the use of the ultrasonic scalpel, i.e. the device responsible for the production of these particles.

For what concerns the heavier particles ( $\geq 5 \mu\text{m}$ ), a correlation with the percentage use of the ultrasonic scalpel emerged only with regard to knee-replacement procedures. This could be explained by the fact that, as a proportion of the total particulates released by the ultrasonic scalpel, which is known to produce particulates in the  $0.35\text{--}6.5 \mu\text{m}$  range, particulates with a diameter of  $\geq 0.5 \mu\text{m}$  may prevail; by this token, the heavier particles could account for a smaller proportion of the total, becoming more detectable only after prolonged use of the device.

With regard to the correlation between  $\geq 5 \mu\text{m}$  particles and the number of persons present in the room, the results obtained could be explained in terms of the fact that such particulates also

includes the skin debris, the dimensions of which vary from  $2.5$  to  $20 \mu\text{m}$  [18], and which are constantly being released by both theatre staff and patients. Moreover, the number of persons present influences the amount of movement taking place in the room, which, as already pointed out in other papers [18], tends to raise any dust that has already settled. Likewise, this can explain the correlation between microbial concentration and the number of persons present in the room.

In conclusion, this study showed that the use of surgical instruments that produce surgical smoke, such as the ultrasonic scalpel, can markedly contribute to the production of airborne particulates. However, neither fraction of these particulates ( $\geq 0.5 \mu\text{m}$  or  $\geq 5 \mu\text{m}$ ) displayed any correlation with the microbial load in either of the types of procedure considered.

However, one of the limitations of the present research is that only two particulate fractions were studied. We cannot therefore rule out the possibility that there may be a correlation between the number of particles/ $\text{m}^3$  and CFU/ $\text{m}^3$  if particulate fractions in narrower size-ranges are considered, as has been reported by Stocks et al. [9]. Moreover, further investigations should be carried out in operating theaters equipped with laminar-flow ventilation systems, an issue which has not yet been sufficiently addressed in studies of this kind.

Until these issues have been settled, microbiological monitoring remains the most suitable method of evaluating the quality of air in operating theatres.

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## Author Contributions

Conceived and designed the experiments: MLC PO FP. Performed the experiments: GO DP. Analyzed the data: MS. Contributed reagents/materials/analysis tools: PO RG DP. Wrote the paper: AMS MLC.

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# **EXHIBIT DX56**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS



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## Major article

## Air contamination for predicting wound contamination in clean surgery: A large multicenter study



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## Key Words:

Surgical site infection  
Environmental contamination  
Operating room  
Infectious risk  
Laminar airflow  
Ventilation systems

**Background:** The best method to quantify air contamination in the operating room (OR) is debated, and studies in the field are controversial. We assessed the correlation between 2 types of air sampling and wound contaminations before closing and the factors affecting air contamination.

**Methods:** This multicenter observational study included 13 ORs of cardiac and orthopedic surgery in 10 health care facilities. For each surgical procedure, 3 microbiologic air counts, 3 particles counts of 0.3, 0.5, and 5  $\mu\text{m}$  particles, and 1 bacteriologic sample of the wound before skin closure were performed. We collected data on surgical procedures and environmental characteristics.

**Results:** Of 180 particle counts during 60 procedures, the median  $\log_{10}$  of 0.3, 0.5, and 5  $\mu\text{m}$  particles was 7 (interquartile range [IQR], 6.2-7.9), 6.1 (IQR, 5.4-7), and 4.6 (IQR, 0-5.2), respectively. Of 180 air samples, 50 (28%) were sterile, 90 (50%) had 1-10 colony forming units (CFU)/ $\text{m}^3$  and 40 (22%)  $>10$  CFU/ $\text{m}^3$ . In orthopedic and cardiac surgery, wound cultures at closure were sterile for 24 and 9 patients, 10 and 11 had 1-10 CFU/100  $\text{cm}^2$ , and 0 and 6 had  $>10$  CFU/100  $\text{cm}^2$ , respectively ( $P < .01$ ). Particle sizes and a turbulent ventilation system were associated with an increased number of air microbial counts ( $P < .001$ ), but they were not associated with wound contamination ( $P = .22$ ).

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Conflicts of interest: None to report.

**Conclusions:** This study suggests that particle counting is a good surrogate of airborne microbiologic contamination in the OR.

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Surgical site infection (SSI) is a major public health problem; it is the third most common health care–associated infection and contributes to 13%–17% of all such infections.<sup>1,2</sup> Despite development of preventive measures, SSI continues to represent a substantial public health burden. In addition to the endogenous flora, air in the operating room (OR) is usually considered to be a route of microbial entry into an open clean surgical wound. Each individual naturally produces particles that may convey microorganisms. Control of the OR environment via an appropriate ventilation system is therefore critical for SSI prevention.<sup>3,4</sup> Guidelines for SSI prevention often recommend air control in the OR.<sup>5,6</sup> However, there is no consensus on the appropriate method for routine surveillance.

To our knowledge, only 6 studies have assessed the relationship between air particle count and the presence of bacteria in the air, with conflicting results.<sup>7–12</sup> Three studies found a positive correlation and promoted use of particle count to evaluate air quality of the OR; 2 others found a negative correlation. All 5 studies were from single centers, often performed in a single OR and in the absence of personnel. As a result, no current evidence exists for a relationship between particle count and microbial airborne contamination or for the most effective sampling method. At the beginning of the 1980s, Lidwell et al.<sup>13</sup> and Whyte et al.<sup>14</sup> evidenced a correlation between airborne and wound contamination. Moreover, laminar airflow (LAF) was shown to be a major preventive tool against SSI in clean surgery. However, recent studies have called into question the use of LAF. Two recent reviews found no impact of use of LAF on SSI rates.<sup>3,15</sup> Furthermore, a recent cost-effective study pointed out a disadvantage of LAF in comparison with turbulent air treatment in light of medical evidence and the financial burden of such ventilation systems.<sup>16</sup>

In clean surgery, the wound is often contaminated at closure. The proportion of contaminated wounds in cardiac surgery can be as high as 89%, depending on the type of surgery and the microorganism.<sup>17–19</sup> In a quantitative analysis, 89% of sternal wounds grew bacteria before closure, and 26% of them had  $>10^5$  colony forming units (CFU)/g of sternal tissue.<sup>20</sup> Tammelin et al.<sup>17,18</sup> demonstrated that surgical wound contamination may originate from staff skin flora. Staff skin shedding may lead to the spread of microorganisms by air, with occurrence of wound contamination. Despite these observations, the relationship between air particle counts, airborne bacterial contamination, and microbial contamination of the wound at closure remains unclear.

This study aimed to assess the correlation between particle counts, quantities of airborne bacteria, and wound contamination at closure, along with factors affecting air contamination in orthopedic and cardiac surgery.

## MATERIALS AND METHODS

This observational multicenter study was carried out at 10 health care facilities in France and consisted of 5 university hospitals and 5 private hospitals and 13 ORs, 6 in cardiac surgery and 7 in orthopedic surgery. Two clean surgery specialties that used a cutaneous approach were included: cardiac surgery with procedures requiring full median sternotomy (planned coronary artery bypass graft [CABG], valve repair, or replacement surgery) and

orthopedic surgery for total hip and knee replacements. For each surgical specialty, ORs were randomly selected.

Microbiologic air counts were measured using an impactor air sampler (Air-test Omega, LCB, La Salle, France) at a flow rate of 100 L/min for 5 minutes (500 L) on trypticase soy agar (bioMérieux, Marcy l'Etoile, France) and were then incubated for 4 days at 30°C. Air counts were expressed as CFU per cubic meter. The air sampler was positioned at the head of the patient. After each sample the impactor was disinfected. Samples were taken at the time of skin incision, 15 minutes after bone cut (sternum or femur) and at wound closure.

Particle count (HandiLaz Mini, Particle Measuring Systems, Boulder, CO) was performed using a photodetection device continuously from incision to wound closure.<sup>21</sup> The particle analyzer sampled for 1 minute every 3 minutes throughout the surgical procedure at a rate of 0.0283 m<sup>3</sup>/min (1.0 ft<sup>3</sup>/min) and logged data at 1-minute intervals to obtain sample volumes of 0.0283 m<sup>3</sup> (28.3 L) of air. Samples were collected at a distance of 100 cm from the surgical wound at the patient's head. Particles were classified by diameter into the following 3 sizes: 0.3, 0.5, and 5 µm. Counts and particle size measurements were recorded electronically by the particle analyzer from time of patient entry to that of patient exit from the OR.

A sample from the operated wound was performed before closure. We used the sampling method previously described<sup>22</sup> using 7.5 × 7.5 cm sterile pads of polyamide–polyester–viscose. Pads were placed on subcutaneous tissue and removed after being soaked by wound liquids for 1 minute. Sampling was performed prior to antiseptic aspersion. Microorganisms were extracted by vortexing the pads for 2 minutes in phosphate buffer with Tween 80 at 2% and lecithin at 0.3% (Hyphen-BioMed, Neuville-sur-Oise, France), inactivating antiseptic compounds. For each pad, an aliquot of 0.5 mL of phosphate buffer was cultured on blood agar after 48 hours of aerobic and anaerobic incubation, and colonies were counted without further identification.

Information was collected on (1) the surgical procedure, including the surgical specialty, procedure and technique used, incision time, preselected procedure periods previously described, and closure time; and (2) surgical environment characteristics, including type of air filtration, either LAF or turbulent airflow, air changes per hour, positive pressure, and particle contamination class. The architecture of the OR was also collected, including size and volume.

Descriptive analysis of parameters collected was performed. For continuous variables, indicators such as the mean, SD, minimum, median, quartiles, and maximum values were calculated. For particle counting, the mean of the 3 counts performed before, during, and after 5-minute air microbial sampling was calculated. Then, the mean was log<sub>10</sub> transformed. Numbers of CFU cultured from wounds in aerobic and anaerobic media were added up and computed to obtain the number of CFU per centimeter squared of wounds. Then, results of the wound culture were categorized into 3 classes: negative culture, 1–10, and  $>10$  CFU/100 cm<sup>2</sup>. Microbiologic air counts were also categorized into the following 3 different classes: negative, 1–10, and  $>10$  CFU/m<sup>3</sup>. Univariate comparisons used a Wilcoxon rank or  $\chi^2$  test as required. A multinomial logistic regression model with the generalized estimating equation for repeated measures was used to assess the link between air particle

**Table 1**  
Procedures included in the study

Characteristics	Orthopedic surgery (n = 34)	Cardiac surgery (n = 26)	P value
Type of hospital			
University hospital	21 (61.8)	9 (34.6)	<.01
Private hospital	13 (38.2)	17 (65.4)	NA
Type of procedure			
Total knee replacement	17 (50)	NA	NA
Total hip replacement	17 (50)	NA	NA
CABG	NA	11 (42.3)	NA
CABG + VR	NA	4 (15.4)	NA
Valve replacement	NA	11 (42.3)	NA
Sequence of the operation during the day			
First	19 (55.9)	26 (100)	<.01
Second	11 (32.4)	0 (0)	NA
Third	4 (11.8)	0 (0)	NA
Type of airflow			
Turbulent	13 (38.2)	22 (84.6)	<.01
Unidirectional	21 (61.8)	4 (15.4)	NA
Air change rate per hour	57.6 (57.1-65)	49.8 (44-63.9)	.02
Positive pressure, Pa	20 (19-42)	19 (12-33)	.91
Volume of the OR, m <sup>3</sup>	105 (102-136)	124 (101-134)	.88
No. of doors	2 (1-2)	2 (1-3)	.43
Surfaces, m <sup>2</sup>	39.4 (34-46)	39 (36-46.9)	.51

NOTE. Values are mean (IQR), n (%), or as otherwise indicated.

CABG, coronary bypass graft; IQR, interquartile range; NA, not applicable; OR, operating room; VR, valve repair or replacement.

counts, microbiologic air counts, and contamination of the wound at closure, after adjustment for the type of air treatment and the rank of sampling during the surgical procedure. Finally, a hierarchical model with a random effect at the patient level and OR level was performed to adjust for contextual variation in the analysis. SAS version 9.3 statistical software (SAS Institute, Cary, NC) was used to perform all analyses. This protocol was approved by the Institutional Review Board of the Paris North Hospitals, Paris 7 University, AP-HP (no. 11-113; April 6, 2012).<sup>23</sup>

## RESULTS

Overall, 60 surgical procedures were included: 34 in orthopedic surgery (17 total knee replacements, 17 total hip replacements) and 26 in cardiac surgery (11 CABGs, 11 valve repairs, 4 combined CABGs and valve repairs) (Table 1). In cardiac surgery, only the first procedure of the day in the OR was included. In orthopedic surgery, 19 procedures were in first position, 11 were in second position, and 4 were in third position during the same day. ORs of cardiac surgery had a median surface of 39 m<sup>2</sup> (interquartile range [IQR], 36-47), with 2 doors (IQR, 1-3). The system of air treatment was mainly turbulent airflow (22 of 26, 85%), with a median of 50 (IQR, 44-64) air changes per hour with a positive pressure of 19 (IQR, 12-33) Pa. Orthopedic surgery OR size was 39 m<sup>2</sup> (IQR, 34-46), with 2 doors (IQR, 1-2). Systems of LAF were predominant (21 of 34, 62%), with a median of 58 (IQR, 57-65) air changes per hour and a positive pressure of 20 (IQR, 19-42) Pa. Among the 180 particle counts performed, the median log<sub>10</sub> of 0.3, 0.5, and 5 µm was 7 (IQR, 6.2-7.9), 6.1 (IQR, 5.4-7), and 4.6 (IQR, 0-5.2), respectively (Table 2). The median number of CFU in air sampling was 4 (IQR, 0-9) per cubic meter with 50 (28%) sterile samples, 90 (50%) with 1-10 CFU/m<sup>3</sup>, and 40 (22%) with >10 CFU/m<sup>3</sup>. For this last category, the median number of CFU in air sampling was 20.5 (IQR, 14-29.5; range, 11-47) per cubic meter, mainly in cardiac surgery (n = 36) with a turbulent ventilation system (n = 38). Among the 60 cultures of wound samples, 33 were sterile, 21 had 1-10 CFU/100 cm<sup>2</sup>, and 6 had >10 CFU/100 cm<sup>2</sup>. Wounds in orthopedic surgery were significantly less contaminated at closure than in cardiac surgery (24 vs 9 sterile

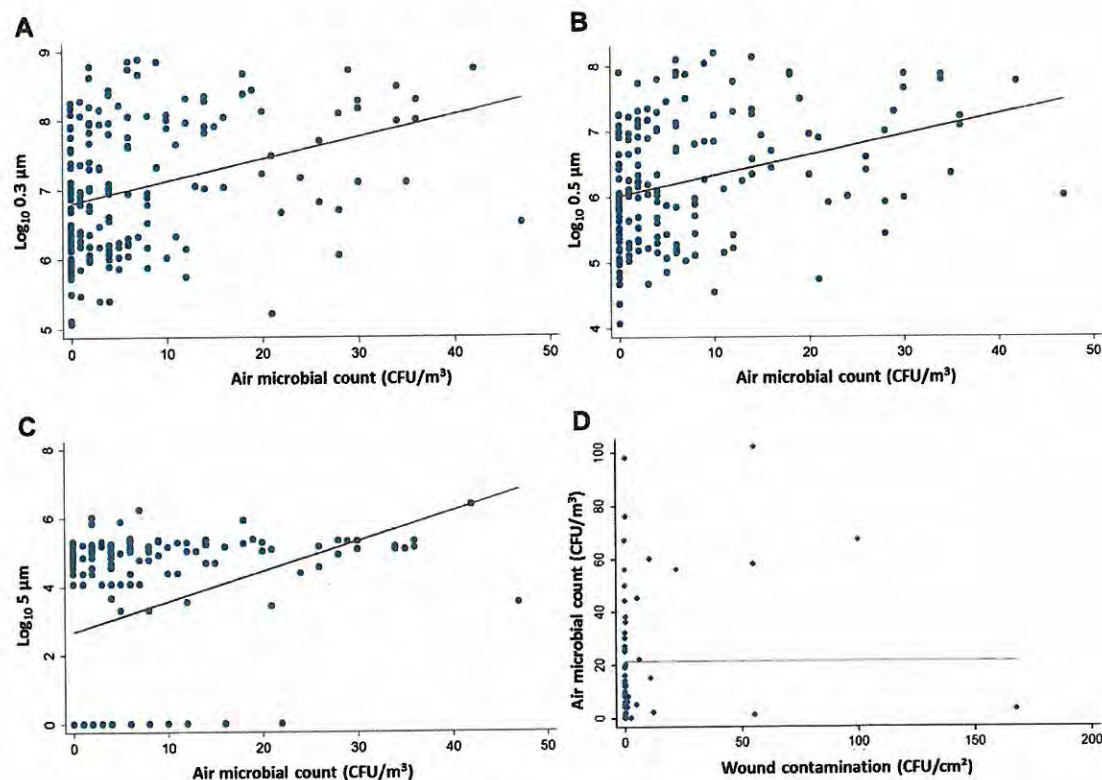
**Table 2**  
Distribution of particle counts, airborne bacteria, and wound contamination

Variable	Overall (N = 60)	Orthopedic surgery (n = 34)	Cardiac surgery (n = 26)	P value
Time 1: incision				
Air microbiologic sampling	4.5 (0-10)	2.5 (0-6)	11 (2-20)	<.01
0	16 (26.7)	12 (35.3)	4 (15.4)	<.01
1-10	30 (50)	21 (61.8)	9 (34.6)	
>10	14 (23.3)	1 (2.9)	13 (50)	
Log <sub>10</sub> of 0.3 µm	7.8 (7.1-8.1)	7.5 (7-8)	8 (7.7-8.3)	.03
Log <sub>10</sub> of 0.5 µm	6.9 (6.4-7.3)	6.8 (6-7)	7.1 (6.7-7.8)	<.01
Log <sub>10</sub> of 5 µm	4.8 (3.9-5.2)	4.8 (0-5.2)	5.1 (4.5-5.3)	.11
Time 2: after bone cut				
Air microbiologic sampling	3 (0-7.5)	1.5 (0-4)	5 (2-18)	<.01
0	17 (28.3)	15 (44.1)	2 (7.7)	<.01
1-10	31 (51.7)	18 (52.9)	13 (50)	
>10	12 (20)	1 (2.9)	11 (42.3)	
Log <sub>10</sub> of 0.3 µm	6.9 (6.2-8)	6.3 (6.1-7)	7.6 (6.9-8.2)	<.01
Log <sub>10</sub> of 0.5 µm	6.1 (5.4-7.1)	5.6 (5.2-6.1)	7 (6.1-7.3)	<.01
Log <sub>10</sub> of 5 µm	4.4 (0-5.2)	4.4 (0-5)	4.6 (0-5.2)	.54
Time 3: wound closure				
Air microbiologic sampling	4 (0-9)	2 (0-5)	9 (3-17)	<.01
0	17 (28.3)	12 (35.3)	5 (19.2)	<.01
1-10	29 (48.3)	20 (58.8)	9 (34.6)	
>10	14 (23.3)	2 (5.9)	12 (46.2)	
Log <sub>10</sub> of 0.3 µm	6.3 (6-7)	6.2 (5.9-6.5)	6.6 (6.1-7.1)	.04
Log <sub>10</sub> of 0.5 µm	5.5 (5.2-6.1)	5.4 (5.1-5.9)	6 (5.2-6.3)	.05
Log <sub>10</sub> of 5 µm	4.1 (0-5)	4.1 (0-4.9)	4.2 (0-5)	.22
Total				
Air microbiologic sampling	4 (0-9)	2 (0-5)	8.5 (2-20)	<.01
0	50 (27.8)	39 (38.2)	11 (14.1)	<.01
1-10	90 (50)	59 (57.8)	31 (39.7)	
>10	40 (22.2)	4 (3.9)	36 (46.2)	
Log <sub>10</sub> of 0.3 µm	7 (6.2-7.9)	6.5 (6.1-7.3)	7.4 (6.8-8.1)	<.01
Log <sub>10</sub> of 0.5 µm	6.1 (5.4-7)	5.9 (5.2-6.7)	6.6 (6-7.3)	<.01
Log <sub>10</sub> of 5 µm	4.6 (0-5.2)	4.5 (0-5)	4.8 (0-5.2)	.06
Wound culture, CFU/cm <sup>2</sup>	0 (0-0.6)	0 (0-3)	0.3 (0-6.1)	<.01
0	33 (55)	24 (70.6)	9 (34.6)	<.01
1-10	21 (35)	10 (29.4)	11 (42.3)	
>10	6 (10)	0	6 (23.1)	

NOTE. Values are n (%), median (interquartile range), or as otherwise indicated. CFU, colony forming units.

cultures, 11 vs 10 with 1-10 CFU/100 cm<sup>2</sup>, and 0 vs 6 with >10 CFU/100 cm<sup>2</sup>, respectively). The median duration of procedures from incision to closure was 114 minutes (IQR, 80-208) in orthopedic surgery and 121 minutes (IQR, 72-141) in cardiac surgery.

Distribution of the log<sub>10</sub> of particle counts according to the 3 classes of air microbial counts in the 180 couples of air sampling are presented in Figure 1. The median number of log<sub>10</sub> of 0.3 µm particles increased from 6.4 for sterile air samples to 7.9 when >10 CFU/m<sup>3</sup> were cultured. The same trend was observed for log<sub>10</sub> of 0.5 µm particles (from 5.8-6.8) and log<sub>10</sub> of 5 µm particles (from 0-5.1). Univariate multinomial logistic regression found significant positive associations between the 3 classes of microbial contamination from air samples and the log<sub>10</sub> of 0.3 µm particles ( $P < .001$ ), log<sub>10</sub> of 0.5 µm particles ( $P < .001$ ), and log<sub>10</sub> of 5 µm particles ( $P < .001$ ) (Table 3). These variables remained associated after adjustment for the type of ventilation system and time of sampling. The turbulent ventilation system was also positively associated ( $P < .001$ ) with a higher number of air microbial counts in the 3 multivariate models. The hierarchical model with random effects on the patient and OR found a significant association between air microbial counts and log<sub>10</sub> of 0.3 µm particles ( $P = .027$ ), but not for the other particle sizes. The turbulent ventilation system remained associated with higher air microbial counts in the 3 hierarchical



**Fig 1.** Distribution of particle counts according to air microbial counts [(A)–(C)] and air microbial counts according to wound contamination at closure (D). CFU, colony forming units.

models. After stratification for type of ventilation system, hierarchical models found an increased positive association between air bacterial counts and particle counts according to the size of particles ( $\log_{10}$  of  $0.3 \mu\text{m}$ ,  $P = .001$ ;  $\log_{10}$  of  $0.5 \mu\text{m}$ ,  $P = .004$ ;  $\log_{10}$  of  $5 \mu\text{m}$ :  $P = .049$ ) in turbulent airflow. However, for operations performed under LAF, the number of air bacterial counts was not statistically associated with particle counts. After stratification for type of surgery,  $\log_{10}$  of  $0.5 \mu\text{m}$  particles ( $P = .01$ ) and turbulent ventilation system ( $P = .05$ ) were still associated with higher air microbial counts after adjustment in orthopedic surgery. In cardiac surgery, the 3 sizes of particles and the turbulent ventilation for the 2 lower sizes were significantly associated with higher air microbial counts ( $P < .01$ ).

Univariate and multivariate analyses of the association between wound cultures are displayed in Table 4. Wound contamination did not significantly differ according to air microbial count among the 60 samples ( $P = .22$ ). This association remained nonsignificant after adjustment for type of airflow and length of surgery ( $P = .39$ ). However, the turbulent airflow system was significantly associated with increased wound contamination in the multivariate model ( $P = .05$ ).

## DISCUSSION

This study was performed to assess the correlation between 3 surrogates of environmental infectious risk in the OR and the influence of the air ventilation system. In this multicenter study, results suggest that microbial contamination of air samples taken during 60 operations in 13 ORs is strongly correlated with particle counts. The turbulent air system was also associated with significantly increased air microbial contamination in comparison with LAF. However, we did not find a significant relationship between air

microbial contamination and wound contamination at closing. Surveillance of proper functioning of OR air ventilation systems is recommended in most guidelines for SSI prevention.<sup>5,6</sup> Evaluation of air contamination may be performed by microbiologic air counts using an impactor air sampler. However, this technique is time-consuming and requires skills in environmental microbiology. Particle counting was proposed as an easier alternative for microbial culture with real-time results.<sup>21</sup>

Interpretation of particle count is based on the theory that particles may shed organisms, and their number constitutes a surrogate of airborne microbial contamination. However, the association between particles and organisms is far from being clearly established. Several studies evaluated it in the OR, but these studies had frequent limitations. The limitations included the following: sampling in an empty OR (which does not reflect actual contamination during surgical procedures), a limited number of samples, and the type of OR sampled. These studies were all performed at a single center, in ORs with turbulent air ventilation systems probably presenting varying characteristics.<sup>7–12</sup> In addition, confounding variables were rarely assessed in the statistical models. Heterogeneity in the studies probably contributed to conflicting results. In our study, the particle count reflected the number of organisms in the air in the 3 particle sizes, in ORs with turbulent air ventilation systems. The  $5 \mu\text{m}$  particle count is usually considered as reflecting microbial contamination because of similarity in size with bacteria. However, the 3 types of particle size were strongly correlated with airborne bacterial counts and likely represent a surrogate of overall air contamination during the surgical procedure. Such associations were not found in ORs with LAF. The low number of particle counts in ORs with LAF could explain the absence of a positive correlation with airborne organisms caused by insufficient power. Results of the present study argue for the use of

**Table 3**

Multivariate models for estimating the association between airborne microbial and particle counts (0.3, 0.5, and 5  $\mu\text{m}$ ) among the 180 observations, adjusted on the type of ventilation and the period of sampling

Models	Crude analysis			Adjusted model			Hierarchical model		
	Estimates	OR (95% CI)	P value	Estimates	OR (95% CI)	P value	Estimates	OR (95% CI)	P value
<b>Model 1</b>									
Log <sub>10</sub> of 0.3 $\mu\text{m}$	0.75	2.1 (1.5-2.8)	<.001	0.89	2.4 (1.5-3.9)	<.001	0.63	1.9 (1.1-3.3)	.03
Laminar airflow			NA	Ref	1	NA	Ref	1	NA
Turbulent airflow				1.64	5.2 (2.3-11.8)	<.001	3.10	22.3 (2.4-202.5)	.01
Period of sampling no. 1			NA	Ref	1	NA	Ref	1	NA
Period of sampling no. 2				0.42	1.5 (0.8-2.8)	.19	0.17	1.2 (0.5-2.9)	.71
Period of sampling no. 3				1.07	2.9 (1.3-6.7)	.01	0.68	1.9 (0.7-5.6)	.20
Random effect: patient	NA		NA	NA		NA	0.50		NA
Random effect: operating room	NA		NA	NA		NA	2.49		NA
<b>Model 2</b>									
Log <sub>10</sub> of 0.5 $\mu\text{m}$	0.71	2.04 (1.5-2.8)	<.001	0.78	2.2 (1.3-3.5)	.001	0.43	1.5 (0.9-2.6)	.12
Laminar airflow			NA	Ref	1	NA	Ref	1	NA
Turbulent airflow				1.62	5.04 (2.3-11.5)	.001	3.11	22.4 (2.4-206.7)	.01
Period of sampling no. 1			NA	Ref	1	NA	Ref	1	NA
Period of sampling no. 2				0.29	1.3 (0.7-2.5)	.37	0.03	1.04 (0.4-2.5)	.94
Period of sampling no. 3				0.91	2.5 (1.1-5.6)	.03	0.43	1.5 (0.5-4.3)	.42
Random effect: patient	NA		NA	NA		NA	0.48		NA
Random effect: operating room	NA		NA	NA		NA	2.52		NA
<b>Model 3</b>									
Log <sub>10</sub> of 5 $\mu\text{m}$	0.35	1.4 (1.2-1.7)	<.001	0.30	1.3 (1.6-1.6)	<.001	0.08	1.08 (0.9-1.3)	.41
Laminar airflow			NA	Ref	1	NA	Ref	1	NA
Turbulent airflow				1.62	5.1 (2.3-11.2)	<.001	3.17	23.7 (2.5-226)	.01
Period of sampling no. 1			NA	Ref	1	NA	Ref	1	NA
Period of sampling no. 2				0.10	1.1 (0.6-1.9)	.73	-0.16	0.8 (0.4-1.9)	.70
Period of sampling no. 3				0.31	1.4 (0.8-2.4)	.27	0.01	1.01 (0.4-2.3)	.98
Random effect: patient	NA		NA	NA		NA	0.44		NA
Random effect: operating room	NA		NA	NA		NA	2.60		NA

NOTE. Models are hierarchical models with random effect on the patient and operating room. CI, confidence interval; NA, not applicable. OR, odds ratio; Ref, reference.

**Table 4**

Univariate and multivariate analysis of the association between the 3 categories of wound contamination (0, 1-10, and >10 CFU/100  $\text{cm}^2$ ) and air microbial counts, type of airflow, and type of procedure

Variables	Crude analysis				Adjusted analysis		
	Wound contamination, CFU/100 cm <sup>2</sup>			P values	Estimates	OR (95% CI)	P values
	0	1-10	>10				
	(n = 33)	(n = 21)	(n = 6)				
Procedure							
Cardiac surgery	9 (27.3)	11 (52.4)	6 (100)	<.001	NA		NA
Orthopedic surgery	24 (72.7)	10 (47.6)	0		NA		NA
Type of airflow					NA		NA
Turbulent	14 (42.4)	15 (71.4)	6 (100)	.01	1.28	3.6 (1.02-12.5)	.05
Unidirectional	19 (57.6)	6 (28.6)	0		Ref		NA
Time from incision to closure, min	145 (116-221)	184 (144-272)	279 (263-326)	.02	0.004	1 (1-1.01)	.16
Air microbial count, time 1	3 (0-7)	6 (2-10)	16.5 (2-42)	.09	NA		NA
Air microbial count, time 2	3 (0-5)	2 (0-6)	14 (1-30)	.16	NA		NA
Air microbial count, time 3	2 (0-6)	4 (1-12)	11 (0-21)	.39	NA		NA
Overall air microbial count	10 (4-25)	12 (4-36)	57 (3-67)	.22	0.01	1 (0.9-1.03)	.39

NOTE. Values are median (interquartile range), n (%), or as otherwise indicated. CFU, colony forming units; CI, confidence interval; NA, not applicable; OR, odds ratio.

particle counts for routine evaluation of air ventilation in an OR with turbulent airflow. Air contamination was not significantly associated with wound contamination. A large number of surgical wounds (up to 89% in cardiac surgery) are contaminated at closure.<sup>17-19</sup> Organisms may be endogenous and arise from patient skin flora, or they may be exogenous, arising from the surgical team or in the air. This combination of endogenous and exogenous organisms can confound the relationship between the quantitative presence of organisms in the air and those colonizing the wound during surgery. In addition, the rather low number of wound samplings might not suffice for attaining a statistical association.

The selection of an air system for clean surgery has recently been strongly debated in surgical and infection control

communities. The LAF has long been considered the best system for obtaining ultraclean air and limiting the environmental SSI risk.<sup>13</sup> LAF has been promoted on the basis of quality criteria obtained in empty ORs. However, during operations, many events may disrupt the laminarity of airflow, including the presence of surgical staff at the surgical site, lighting (scalytic), and door opening. Several recent studies and systematic reviews found no effect of LAF on SSI rates.<sup>3,15</sup> Moreover, LAF was considered a risk factor in SSI, with 2 main adverse effects (ie, a decrease in the patient's temperature, encroachment into surgical wounds) of organisms conveyed by elements located beneath the airflow.<sup>3</sup> After adjustment, we found a significant association between LAF and low air bacterial counts, suggesting that additional clinical studies with prospective and

appropriate designs are required to assess the impact of LAF on clean surgery.

The design and method used for data analysis, including multiple adjustments, were major strengths of our study. To our knowledge, this study was the largest performed thus far and the only multicenter study that included different ORs and different clean surgical specialties. The analysis, including accurate statistical methods, took into account variability in architectural characteristics, ventilation systems, and organization, with an accurate statistical method for adjustment. The generalized estimating equation was used to avoid potential unknown correlations between outcomes because of the multicenter design of the study. Hierarchical modeling enabled estimating associations after inclusion of the patient and OR effects in the analysis. The study also had several limitations. First, we analyzed the 3 particle counts simultaneously with the air microbial count, but particle counts can vary greatly and rapidly over time. Second, samples were performed in the same area, but they were not at exactly the same site. Third, we did not take into account other parameters possibly interfering with air count (eg, door openings, the number of persons in the OR, movement). Finally, the strains cultured from the air and the wound were not identified. We considered these samples as quantitative surrogates of the environmental infectious risk.

We found a strong correlation between air particle counts and microbial contamination, suggesting that particle counting can be used for routine evaluation of contamination in the OR ventilated with turbulent airflow or LAF. Moreover, LAF was associated with decreased air microbial contamination in clean surgery, suggesting that further studies are needed to assess its impact on infectious risk in the OR.

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# **EXHIBIT DX57**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In Re: Bair Hugger Forced Air )  
Warming Products Liability )  
Litigation )  
This Document Relates To: )  
All Actions. ) MDL No.  
15-2666 (JNE/FLN)  
\_\_\_\_\_)

VIDEOTAPED DEPOSITION OF SAID ELGHOBASHI  
Newport Beach, California  
Thursday, June 15, 2017

Reported by:  
ELIZABETH BORRELLI, CSR No. 7844, CCRR, CLR  
JOB NO. 124785

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1 was referring to this meeting that you asked. Okay.  
 2 Reading, meeting. So in August -- on August 28th,  
 3 we met at UCI, and at that time, that was the first  
 4 time I see the Bair Hugger and the blanket and we  
 5 made a test at that time.

6 [Reporter requests clarification.]

7 THE WITNESS: A test.

8 BY MR. GORDON:

9 Q. What test did you do at that time?

10 A. So we put Gabriel on the table like this,  
 11 a conference room, and we cover him with the Bair  
 12 Hugger blanket and we activated the -- the blower,  
 13 the BH blower.

14 Q. Okay. I'm going to anticipate this  
 15 because I think this is -- is that Exhibit 8, is  
 16 that the number you wrote?

17 MS. ANDREWS: That's correct.

18 THE WITNESS: That's something else. Then  
 19 this is -- we --

20 MS. ANDREWS: There's no question pending,  
 21 Doctor.

22 THE WITNESS: Okay. That is --

23 MR. GORDON: I'm just --

24 THE WITNESS: That's something else.

25 BY MR. GORDON:

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1 Q. I'm -- I'm showing Exhibit 8, a series of  
 2 four photographs that were --

3 A. Correct, yes.

4 Q. -- produced to us this morning.

5 A. Uh-huh.

6 Q. What -- what are these photographs of?

7 A. These were in operating room in Santa  
 8 Monica, California. I don't know the date, but it  
 9 could be September 2016. And we put a volunteer  
 10 patient on an operating --

11 MS. ANDREWS: He doesn't have a question  
 12 pending.

13 THE WITNESS: Okay.

14 MS. ANDREWS: You have to wait for him --

15 THE WITNESS: Okay.

16 MS. ANDREWS: -- to direct you --

17 THE WITNESS: Okay. Okay.

18 MS. ANDREWS: -- to what he wants to know  
 19 about the photos.

20 THE WITNESS: Okay.

21 BY MR. GORDON:

22 Q. Why don't you tell me what those photos  
 23 depict.

24 A. So in an operating room, we asked a  
 25 registered nurse to set up the operating table and a

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1 blanket and the drapes as she usually does, and we  
 2 asked the volunteer patient to lie down and we run  
 3 the BH blower.

4 Q. When you say "we," who else was present?

5 A. Ms. Anne Andrews and John and another  
 6 counsel, Leila -- I don't know her last name.

7 Q. Anyone other -- besides lawyers and the --  
 8 this RN?

9 A. The RN, they were -- there was a company.  
 10 We wanted to see if they can do a CAD for this room.

11 MR. GORDON: So we're up to Exhibit 12.

12 (Whereupon Exhibit 12 was marked for  
 13 identification.)

14 BY MR. GORDON:

15 Q. I'm going to show you what -- what I've  
 16 marked as Exhibit 12. Does that appear to be a copy  
 17 of your expert report in this matter? Is that -- is  
 18 this your expert report, Exhibit 12?

19 A. Correct.

20 Q. Okay.

21 A. It looks like.

22 Q. Okay. And if you turn to page 10 of  
 23 Exhibit 12, there appears to be a -- a computer --

24 A. Yes.

25 Q. -- assisted drawing --

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1 A. Yes.

2 Q. -- at the bottom. Is -- was this done by  
 3 the company that you were -- you're talking about,  
 4 in the lower left-hand corner, Figure 4(a)?

5 A. No, that -- that is not done by that  
 6 company, no.

7 Q. Did that company do any --

8 A. No, they -- they couldn't.

9 Q. Okay.

10 A. They couldn't.

11 MS. ANDREWS: Wait. You need to wait for  
 12 him to --

13 THE WITNESS: Oh, okay.

14 MS. ANDREWS: -- finish his question.

15 THE WITNESS: Okay. Okay.

16 MR. GORDON: Well --

17 MS. ANDREWS: Objection. Calls for  
 18 attorney work product.

19 You can answer.

20 BY MR. GORDON:

21 Q. Well, what was your understanding of why  
 22 they couldn't do it? Was it a computer problem  
 23 or --

24 A. They were using -- yeah, but --

25 MS. ANDREWS: If you know.

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1 MS. ANDREWS: Yeah, the -- Counsel, let's  
2 just be clear. The new rules do not permit any --  
3 and I believe that these are the rules that have  
4 been in play in this case with your witnesses and  
5 will be with your witnesses, that we are not -- and  
6 are not required to go into background  
7 conversations, drafts, communications with counsel  
8 are all off limits and I will be instructing him not  
9 to answer unless I hear a question that's properly  
10 posed to the witness.

11 BY MR. GORDON:

12 Q. I -- I'm not asking you if your -- if the  
13 attorneys you're -- you're working for typed up  
14 your -- your report. I'm assuming you didn't sit  
15 yourself at a -- at a keyboard and type up the  
16 report.

17 MS. ANDREWS: Objection. Argumentative.  
18 Calls for speculation.

19 Can you -- do you want that question back?

20 THE WITNESS: I would -- I would like to,  
21 yes.

22 MS. ANDREWS: Don't answer any question  
23 that you have not understood. And if I object or  
24 counsel has comments about the question, be sure and  
25 have it read back so it's clear in your mind before

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1 you answer it.

2 THE WITNESS: I typed this report.

3 BY MR. GORDON:

4 Q. Okay. Did you have any graduate students  
5 assist you in any aspect of this report?

6 A. Yes.

7 Q. Who?

8 A. That would be Dr. Apte, A-P-T-E. He's a  
9 professor.

10 Q. Is he at Stanford?

11 A. He used to be at Stanford. He's now at  
12 Oregon State.

13 Q. Oregon State. Okay.

14 And what did Dr. Apte -- what were -- what  
15 was Dr. Apte's contribution to the -- to your  
16 report?

17 A. Running the computer program.

18 Q. The -- the code for the model?

19 A. Correct, yes.

20 Q. Okay. And, in fact, the -- the code that  
21 was used is proprietary code of Dr. Apte's, correct?

22 A. Correct.

23 MS. ANDREWS: Yeah.

24 BY MR. GORDON:

25 Q. So Dr. Apte actually ran the -- the

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1 model --

2 A. Correct.

3 Q. -- correct?

4 Based on boundary conditions that you  
5 provided to him, right?

6 A. Correct.

7 Q. Okay. Did Dr. Apte participate in  
8 actually dev- -- developing the -- the boundary  
9 conditions?

10 A. No. I did.

11 Q. Okay. Was he physically present, you  
12 know, in Santa Monica when you went into that  
13 operating room?

14 A. No.

15 Q. Was he physically present for any aspect  
16 of this, or was this just something where he, up in  
17 Oregon, ran the -- ran the code?

18 A. So we met few times.

19 Q. Where?

20 A. At APS meet- -- American Physical Society  
21 meeting in Portland.

22 Q. Okay. When -- do you know when that was?

23 A. This was in November, before Thanksgiving.

24

25 Q. Now, did he charge for his work?

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1 A. Correct.

2 Q. Did he bill the plaintiffs separately for  
3 that?

4 A. No. He -- only with me.

5 Q. Okay. And did -- did you then bill the  
6 plaintiffs' counsel for Dr. Apte's work?

7 A. Correct.

8 Q. Okay. Let's -- we -- we're jumping around  
9 a little bit because I'm just trying to put things  
10 together.

11 A. Yeah.

12 Q. 9C is the -- is the third invoice that was  
13 provided this morning. What -- and that -- I --  
14 what -- what's the period of time that that covers?

15 A. February 17 to March 17.

16 Q. 2017, right?

17 A. Correct.

18 Q. Okay. So in those three invoices, 9A, 9B  
19 and 9C, I don't see any reference to a payment for  
20 Dr. Apte or any -- any other outside consultant.  
21 Did I -- did I miss it or would -- would there have  
22 been some other invoice?

23 A. Right. I -- I paid Dr. Apte. I paid him  
24 after I get the funds from the counsel.

25 Q. Okay. But in order to get the funds from

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1 question again, please?

2 BY MR. GORDON:

3 Q. Well, I -- I'm trying to understand where  
4 you got the information that you used for your  
5 boundary conditions with respect to temperature.  
6 And I want to make sure I'm -- I -- I under- --  
7 understand where you got that.

8 A. Okay.

9 Q. I thought I heard you say earlier that the  
10 only thing you got from the YouTube video were the  
11 dimensions of the room. Reading this, it seemed  
12 that you also got the temperature conditions.

13 MS. ANDREWS: Objection. Mischaracterizes  
14 prior testimony.

15 BY MR. GORDON:

16 Q. So I'm just -- I just want to be clear. I  
17 want to -- if you turn to page 33, under Table 2,  
18 under temperature of hot air leaving the drape  
19 edge --

20 A. Uh-huh, yes.

21 Q. -- you have 41.11 degrees --

22 A. Correct.

23 Q. -- Celcius, and that appears to be the  
24 same number that you list on page 32 as having been  
25 "according to 3M video."

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1 A. Yes.

2 Q. Okay. So where did you get the 42 -- the  
3 -- where did you get the -- the temperature of  
4 41.11 degrees Celcius for the temperature of hot air  
5 leaving the drape edge as you list on Table 2?

6 A. Okay. From the 3M video, yes.

7 Q. Okay. So that -- and that would -- that's  
8 one of the boundary conditions that you provided to  
9 Dr. Apte, correct?

10 A. Yeah, we usual -- okay, yes.

11 Q. Okay. Did you do anything to verify that  
12 41.11 degrees Celcius temperature as being a -- a  
13 correct boundary condition for the temperature of  
14 hot air leaving the drape edge?

15 A. Yes. There is a 3M table, which is one of  
16 the exhibits, that showed the model and the blanket  
17 and -- and it shows sometimes even higher than 41,  
18 like, 41.6.

19 Q. When you say one of the exhibits, it's  
20 something in your report or --

21 A. No. It's -- was given you today.

22 Q. Oh, okay.

23 If you see it, call out, because I --

24 THE WITNESS: This one.

25 MS. ANDREWS: You can thank me now,

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1 Counsel. It's this exhibit that we gave to you  
2 earlier to -- for the record.

3 THE WITNESS: Yeah.

4 MS. ANDREWS: Our 3M tables.

5 BY MR. GORDON:

6 Q. Okay. So you're -- what you're referring  
7 to just a moment ago as the verification of the --

8 A. Correct.

9 Q. -- 41.11 is Exhibit --

10 A. Uh-huh.

11 Q. -- is that 1D?

12 MS. ANDREWS: It was previously marked  
13 when we gave it to you as --

14 THE WITNESS: 1D.

15 MS. ANDREWS: -- 1D.

16 THE WITNESS: Like David.

17 BY MR. GORDON:

18 Q. Okay.

19 A. And -- yes. So here, the new model, 750,  
20 and then the blanket, 522, and you can see -- yeah,  
21 it's even -- it even reaches 42.4. It's higher,  
22 yeah.

23 BY MR. GORDON:

24 Q. Is it -- before you hand me -- hand that  
25 back to me, can you -- can you show me, is there

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1 anywhere on Exhibit 1D that indicates that the --  
2 any of the temperatures listed there are a  
3 reflective of the temperature of air that would be  
4 exiting the edge of a drape over the patient and the  
5 Bair Hugger blanket?

6 A. None.

7 Q. Okay. And on the YouTube video, is it  
8 your recollection that the temperatures -- the  
9 temperature that was given of 106 degrees  
10 Fahrenheit, that the -- that -- is it your  
11 recollection that the video indicated that that was  
12 the temperature of the air leaving the drape edge?

13 A. I don't recall the video, of what it said  
14 on the video. I do not recall.

15 Q. Okay. Did you do any measurements with a  
16 -- you know, take -- take temperatures, you know,  
17 with a thermocouple or a -- some -- some sort of  
18 a --

19 A. It --

20 Q. -- instrument?

21 MS. ANDREWS: Let him finish. Let him  
22 finish.

23 THE WITNESS: No.

24 BY MR. GORDON:

25 Q. Okay. Going back to those four

1 photographs -- what was that exhibit?  
 2 MS. ANDREWS: Eight.  
 3 THE WITNESS: Eight.  
 4 BY MR. GORDON:  
 5 Q. Exhibit 8. Those were taken at UC Irvine?  
 6 A. Nine -- no.  
 7 Q. Oh, I'm sorry. Where were those photos  
 8 taken?  
 9 A. Santa Monica.  
 10 Q. Oh, I'm sorry. Okay. So those  
 11 photographs --  
 12 A. From Santa Monica.  
 13 Q. I see. Okay. How -- how was it that you  
 14 gained access to an operating room at -- in Santa  
 15 Monica? Is that something you arranged?  
 16 A. No.  
 17 Q. Do you know who arranged it?  
 18 A. The counsel.  
 19 Q. Okay. And do -- what -- was it -- what  
 20 type of operating room was it that you were given  
 21 access to?  
 22 A. Orthopedic surgery operating room.  
 23 Q. Okay. And what time of day was it?  
 24 A. We arrived at 9:00 o'clock and we stayed  
 25 until late.

1 Hugger?  
 2 A. Correct.  
 3 Q. Did you take any temperature measurements?  
 4 A. No.  
 5 Q. Did you take any velocity measurements?  
 6 A. No.  
 7 Q. Did you take any -- well, the -- the  
 8 Exhibit 4 appears to be a --  
 9 A. The dr- --  
 10 MS. ANDREWS: Wait.  
 11 BY MR. GORDON:  
 12 Q. Let me -- let me finish the question.  
 13 A. Okay.  
 14 Q. It look -- it looks like there's a -- a --  
 15 some sort of a ruler or --  
 16 A. Right.  
 17 Q. -- tape measure depicted in the -- those  
 18 photographs; is that right?  
 19 A. Correct.  
 20 Q. Who is -- can you tell who's holding that?  
 21 It looks like -- I'm -- I'm assuming you don't wear  
 22 nail polish.  
 23 A. Right. So I -- the -- could have been one  
 24 or --  
 25 MS. ANDREWS: If you know.

1 Q. In the evening?  
 2 A. Afternoon, maybe. I don't recall.  
 3 Q. Were -- were there any surgeries being  
 4 performed while you were there?  
 5 A. No.  
 6 Q. Was there any hospital staff present other  
 7 than the RN?  
 8 A. No.  
 9 Q. And I think you said you -- you went to  
 10 Santa Monica, the OR, in was it September of 2016?  
 11 MS. ANDREWS: Objection. Asked and  
 12 answered.  
 13 THE WITNESS: I -- it could be, but I am  
 14 not sure.  
 15 BY MR. GORDON:  
 16 Q. Well, in -- in terms of when you developed  
 17 the boundary conditions that you provided to  
 18 Dr. Apte --  
 19 A. Uh-huh.  
 20 Q. -- would your visit to Santa Monica have  
 21 been before or after you developed those boundary  
 22 conditions?  
 23 A. Before.  
 24 Q. Okay. And when you were in the OR in  
 25 Santa Monica, did you turn on the -- the Bair

1 THE WITNESS: Okay.  
 2 MS. ANDREWS: You don't have guess or  
 3 speculate.  
 4 THE WITNESS: Yeah, I just forgot.  
 5 MS. ANDREWS: If you don't know, you tell  
 6 him you don't know.  
 7 THE WITNESS: Yeah, I don't recall, yeah.  
 8 BY MR. GORDON:  
 9 Q. Would -- the -- the hand that appears  
 10 there, is that the RN, do you know?  
 11 MS. ANDREWS: Objection. Asked and  
 12 answered.  
 13 THE WITNESS: I don't recall.  
 14 BY MR. GORDON:  
 15 Q. Okay. Were you there when the tape  
 16 measure -- measurements were used?  
 17 A. Oh, yes.  
 18 Q. Okay.  
 19 A. Yes.  
 20 Q. What -- what was the purpose of -- of  
 21 doing the tape measurements?  
 22 A. The -- the only thing I can re- --  
 23 MS. ANDREWS: Would you --  
 24 THE WITNESS: Oh.  
 25 MS. ANDREWS: Doctor, I'm really going to

1 have to keep reminding --

2 THE WITNESS: Okay. Okay.

3 MS. ANDREWS: -- you and counsel's going  
4 to be just as annoyed with me as I am with you.  
5 Please do not start your question until after his --  
6 your answer 'til after his question is --

7 THE WITNESS: Okay.

8 MS. ANDREWS: -- absolutely completed.

9 THE WITNESS: Okay.

10 MS. ANDREWS: He -- he's asking them  
11 slowly and you're jumping the gun. So just be  
12 patient and let him get his entire question out to  
13 be fair. Thank you.

14 MR. THORNTON: Keep in mind, this woman  
15 down here has to take all the questions and  
16 answers --

17 THE WITNESS: I'm sorry, yes.

18 MR. THORNTON: -- and if you're speaking  
19 over each other --

20 THE WITNESS: I apologize.

21 MR. THORNTON: -- it can't be done.

22 MR. GORDON: By the time we're done with  
23 this, you'll be a pro. Probably not.

24 BY MR. GORDON:

25 Q. Okay. Why -- just -- why were the

1 measurements taken with the tape measure as  
2 reflected in Exhibit 4?

3 A. To get the geometry of the drape.

4 Q. Were any other measurements or dimensions  
5 taken that day?

6 A. All the drape measurements.

7 Q. So was the main purpose of -- of your  
8 visit to the operating room in Santa Monica that day  
9 to obtain detailed measurements of the -- of the  
10 drapes, or the drape; is that right?

11 A. Not only, yeah.

12 Q. Okay. And that's what -- that's -- that's  
13 fine. That -- that's where I want to go next.

14 A. Okay.

15 Q. What other -- what other things did you --  
16 did you do while you were in that OR?

17 A. To find out where the air leaving, the hot  
18 air of the BH leaving the drape.

19 Q. How did you do that?

20 A. Observing where the air is going from  
21 using -- asking the patient sitting there -- the --  
22 and touching the air that leaves the drape where all  
23 the positions of the drape, yes.

24 [Reporter requests clarification.]

25 THE WITNESS: All the position, yes.

1 BY MR. GORDON:

2 Q. So you -- would -- when you say touch, you  
3 used your hand?

4 A. Uh-huh, correct.

5 Q. Okay. You didn't use any instrumentation?

6 A. Correct.

7 Q. Okay. Now, the patient, do you recall how  
8 the -- the patient was laying on the table? Was --  
9 was -- it looks like a -- is it -- was it a him?  
10 It's hard to tell from that.

11 A. Yeah.

12 Q. Were -- were his hands extended?

13 A. Yes.

14 Q. And the Bair Hugger was across the --

15 A. Correct.

16 Q. -- upper torso -- let me finish -- up --  
17 upper torso and arms; is that right?

18 A. Correct.

19 Q. And it was face -- the -- the holes of the  
20 blanket were facing downward; is that right?

21 A. Correct.

22 Q. Was the blanket -- the Bair Hugger blanket  
23 conformed around the patient's arms in any way?

24 MS. ANDREWS: Objection. Vague and  
25 ambiguous.

1 THE WITNESS: There were ties and the end  
2 of the blanket were tied properly on the arms.

3 BY MR. GORDON:

4 Q. Was the -- and was the blanket -- the  
5 blanket is -- is essentially flat, correct?

6 A. Correct.

7 Q. So when it was laying on the arms of the  
8 mock patient there, were the -- were the sides that  
9 extended beyond the arms folded or curved around the  
10 arms?

11 A. Yes.

12 MS. ANDREWS: Objection. Vague and  
13 ambiguous.

14 BY MR. GORDON:

15 Q. And they were then cinched down with a --  
16 the tie; is that right?

17 A. Correct.

18 Q. And there was a single blanket placed over  
19 it, the -- the Bair Hugger blanket? Or single --  
20 excuse me. Strike that.

21 There was a single drape placed over the  
22 Bair Hugger blanket?

23 MS. ANDREWS: Objection. Vague and  
24 ambiguous.

25 If you don't understand the question,

<p style="text-align: right;">Page 110</p> <p>1 MS. ANDREWS: -- testimony. He wants an 2 answer to his question. 3 THE WITNESS: Okay. 4 MS. ANDREWS: And I want you to give a 5 fair -- 6 THE WITNESS: Sure. 7 MS. ANDREWS: Gave him a fair question, 8 you get a -- 9 THE WITNESS: Sure. 10 MS. ANDREWS: -- fair answer. 11 THE WITNESS: Sure. 12 MS. ANDREWS: Can you please repeat it, 13 Counsel? 14 BY MR. GORDON: 15 Q. Okay. The velocity -- first of all, the 16 velocity is one of the components that -- that 17 allows you to calculate mass flow rate, correct? 18 A. We use the mass flow rate to calculate the 19 velocity, not the other way around. 20 Q. Okay. The mass flow rate is the -- 21 A. Of the blower. 22 MS. ANDREWS: Wait. Don't talk when he's 23 talking. Sorry. 24 BY MR. GORDON: 25 Q. The mass flow rate is a -- is a</p>	<p style="text-align: right;">Page 111</p> <p>1 relationship between the amount of the air moving 2 over a particular area over a period of -- 3 particular period of time, right? 4 A. The mass flow rate that comes from the 5 blower would remain fixed until it leaves the drape 6 edge. 7 Q. Will the velocity remain fixed? 8 A. Never. 9 Q. Okay. Will the temperature remain fixed? 10 A. If the drape is insulated, it would remain 11 without a change. 12 Q. For how long? 13 A. The longer, the better. 14 Q. So a insulated drape that was 100 feet 15 long, if you put the Bair Hugger blanket up against 16 the top of it at the 100 feet below, the -- the 17 temperature would remain exactly the same; is that 18 what you're saying? 19 A. No. 20 Q. Would it be more, less, or what would 21 happen to it? 22 A. It depends on the conditions surrounding. 23 Q. And what -- what are the conditions that 24 will impact it? 25 A. The ambient flow, ambient temperature.</p>
<p style="text-align: right;">Page 112</p> <p>1 Q. And how long will the -- strike that. 2 In your 9E, one of the two charac- -- two 3 boundary conditions you said you would -- you would 4 need in that one sentence we read was the 5 temperature of the blower air, which you then 6 explained you meant the temperature as it comes out 7 of the -- the drape edge. 8 You never measured that temperature, did 9 you? 10 MS. ANDREWS: Objection. Argumentative. 11 Asked and answered. 12 THE WITNESS: I did not. 13 BY MR. GORDON: 14 Q. Okay. The only basis for your boundary 15 condition that you provided to Dr. Apte for the 16 temperature of the air emerging at the edge of the 17 drape was what you gleaned from the YouTube video 18 and Exhibit 1D -- 19 MS. ANDREWS: Objection. 20 BY MR. GORDON: 21 Q. -- is that correct? 22 MS. ANDREWS: Sorry. Objection. 23 Mischaracterizes former testimony. Calls for 24 speculation. Lacks foundation. 25 I'm sorry. You can answer, Doctor, if you</p>	<p style="text-align: right;">Page 113</p> <p>1 have the question in mind. 2 THE WITNESS: And a lot of thinking. 3 BY MR. GORDON: 4 Q. Okay. Why didn't you measure the 5 temperature when you went to Santa Monica? 6 MS. ANDREWS: Asked and answered. 7 Objection. 8 THE WITNESS: I answered that earlier. 9 BY MR. GORDON: 10 Q. I apologize. 11 A. Instruments and -- 12 MS. ANDREWS: Same objection. 13 THE WITNESS: -- and preparation. 14 BY MR. GORDON: 15 Q. And -- and I think we were talking -- I 16 may -- I may have missed it, but we were -- spent a 17 fair amount of time talking about the mass flow 18 rate. Now I'm specifically talking about 19 temperature. And if your answers are the same, 20 that's -- that's fine, but I -- I don't think we 21 talked about temperature. 22 A. Instruments and preparation. 23 Q. Okay. What instruments would you have 24 needed to measure the temperature? 25 MS. ANDREWS: Asked and answered.</p>

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1 THE WITNESS: Anemometers, computers,  
2 software.  
3 BY MR. GORDON:  
4 Q. And you thought it was unnecessary to  
5 obtain those instruments and do the preparation  
6 necessary to actually measure the temperature --  
7 MS. ANDREWS: Objection. Argu- --  
8 BY MR. GORDON:  
9 Q. -- is that right?  
10 MS. ANDREWS: Argumentative. Calls for  
11 speculation. Lacks foundation.  
12 You can answer.  
13 THE WITNESS: I never thought unnecessary.  
14 BY MR. GORDON:  
15 Q. I'm sorry. You never thought it was  
16 unnecessary?  
17 A. Correct.  
18 Q. That's a -- you mean -- so you thought it  
19 was necessary?  
20 A. Yes.  
21 Q. So why didn't you do it?  
22 A. I substituted by thinking hard.  
23 [Reporter requests clarification.]  
24 THE WITNESS: Correct.  
25 BY MR. GORDON:

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1 for speculation.  
2 THE WITNESS: Never better, but  
3 equivalent.  
4 BY MR. GORDON:  
5 Q. Okay. So what did your thought process  
6 entail that you used instead of actual measurements?  
7 A. I cannot answer that.  
8 Q. I'm sorry, you can -- I'm sorry?  
9 A. I cannot answer that.  
10 Q. Okay.  
11 A. It's a complex system.  
12 MS. ANDREWS: Well, wait. Wait. Move to  
13 strike. Withdraw as nonresponsive.  
14 Just tell -- Counsel, will you -- can we  
15 just be -- that question is answerable. I think he  
16 didn't understand it, so if you'll allow him to  
17 answer what his thinking and thought process is, I  
18 won't have to take him on redirect, but -- on  
19 direct, but it's up to you. He has an answer.  
20 BY MR. GORDON:  
21 Q. Do you know what she wants you to say now?  
22 A. No.  
23 MS. ANDREWS: Objection. Move to strike.  
24 BY MR. GORDON:  
25 Q. I mean, I -- I just want to -- I want to

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1 Q. Okay. So had you suggested that that --  
2 that what you wanted to do was actually take  
3 measurements and were told, no, don't?  
4 A. No.  
5 Q. Okay. So you thought it was necessary to  
6 take measurements, but you chose to just think about  
7 it instead?  
8 A. Correct.  
9 MS. ANDREWS: Asked and answered.  
10 Argumentative.  
11 BY MR. GORDON:  
12 Q. What was it that made you decide you were  
13 going to go the thinking route rather than the  
14 measuring route?  
15 A. Experience.  
16 Q. And what about your experience told you  
17 that thinking was the way to go?  
18 Well, let me ask the question a different  
19 way. Have you had any experiences in your very long  
20 and prominent career in -- in computational fluid  
21 dynamics where you found that your thinking about a  
22 boundary issue yielded a better result that actually  
23 measuring it?  
24 MS. ANDREWS: Objection. Unfair --  
25 improper hypothetical. Lacks foundation and calls

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1 find out what your -- what your thinking is, so  
2 please tell me.  
3 MS. ANDREWS: That's right. So do we.  
4 THE WITNESS: Experience means one solves  
5 different problems at all the time from which I can  
6 figure out solutions to something that you cannot  
7 measure for the cir- -- circumstances.  
8 BY MR. GORDON:  
9 Q. When you say you cannot measure, are you  
10 talking about inconvenience or serious impediments  
11 to -- to measurement?  
12 A. Instruments and preparation.  
13 Q. Throughout your career, have you ever used  
14 your thought process in lieu of instruments like  
15 anemometers to measure some important boundary  
16 condition?  
17 A. It depends on the problem.  
18 Q. Can you think of any?  
19 A. You can -- I can rely on previous  
20 experiences to find out what the temperature in that  
21 situation based on other experiences.  
22 Q. Well, what previous experiences did you  
23 rely on to -- to -- to come up with the temperature  
24 boundary condition?  
25 A. I think they are in my resume, in my CV,

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1 Q. As I understand it, you provided the  
2 boundary conditions to Dr. Apte?

3 A. Correct.

4 Q. And he, using his proprietary software,  
5 generated the CFD, right?

6 A. Correct.

7 Q. If those boundary conditions were not  
8 reflective of the real world, then the CFD may be  
9 accurate based on the boundary conditions that you  
10 provided, but it doesn't provide any insight into  
11 the real world, right?

12 A. Disagree.

13 Q. So even if the boundary conditions are  
14 significantly different than real world conditions,  
15 you believe the CFD is -- is an accurate depiction  
16 of the real world conditions?

17 A. The CFD produces accurate results for the  
18 boundary conditions installed in the code.

19 Q. Right. But if the boundary conditions are  
20 incorrect, the CFD is not going to be correct,  
21 right?

22 A. If the boundary conditions -- CFD results  
23 reflect boundary conditions. That's all. So --

24 Q. The boundary conditions that you --

25 A. Correct.

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1 Q. -- gave Dr. Apte to put in, right?

2 A. Correct.

3 Q. And if the boundary conditions you gave  
4 Dr. Apte to put in are inaccurate, then the CFD is  
5 also inaccurate, right?

6 A. I do not give inaccurate boundary  
7 conditions.

8 Q. Okay. In Exhibit 9E, you list nine steps  
9 for which you charged \$120,000, right?

10 A. Yes.

11 MS. ANDREWS: Hold on. What's going on?  
12 Hang on a second.

13 THE WITNESS: Yes.

14 MS. ANDREWS: Got it. I have it.

15 MR. GORDON: Keep that for a moment.

16 BY MR. GORDON:

17 Q. Is there anywhere in that list of nine  
18 steps where you include validation?

19 A. Validation is needed only if you have a  
20 new code you never used before, not validated.

21 Q. So once a code has been validated in one  
22 circumstance --

23 A. Yes.

24 Q. -- it's valid for any set of  
25 circumstances; is that your testimony?

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1 A. If the code was tested for far more  
2 complex situation than the operating room, far more  
3 complex, then it will be accurate for a -- for a  
4 lower level computations.

5 (Whereupon Exhibit 15 was marked for  
6 identification.)

7 BY MR. GORDON:

8 Q. Let me show you Exhibit 15.

9 I'll represent to you that that's a series  
10 of screenshots, but from a -- from a much lengthier  
11 presentation on "Sudden Expansion - Verification &  
12 Validation."

13 You're familiar with this, aren't you?

14 MS. ANDREWS: He asked you if you're  
15 familiar with it.

16 THE WITNESS: Oh, you're asking me?

17 BY MR. GORDON:

18 Q. Yes.

19 A. I thought you were talking to yourself.

20 So which page? Or what -- what you want  
21 me to look?

22 Q. Well, Exhibit 15. You're -- you wrote it,  
23 right?

24 A. Did I write this?

25 Q. You don't recognize it?

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1 MS. ANDREWS: You can take a few minutes  
2 to look at it.

3 THE WITNESS: I -- I -- oh, yeah, this  
4 is -- oh, it's good. This is the course I teach for  
5 undergraduates. Yeah, correct.

6 BY MR. GORDON:

7 Q. Yeah.

8 A. I didn't realize.

9 MS. ANDREWS: I know. Go ahead.

10 BY MR. GORDON:

11 Q. On the first page there it says authors  
12 Yong Wang and Said Elghobashi?

13 A. Well, I didn't read that. I'm sorry. I  
14 never thought this would be on the web. How did  
15 you -- okay. Good.

16 Q. Oh, it's --

17 MS. ANDREWS: Everything's on the  
18 internet, right?

19 MR. GORDON: The web is a mysterious  
20 place.

21 THE WITNESS: Yeah, this is an  
22 undergraduate course, yeah.

23 BY MR. GORDON:

24 Q. Okay. So this is what you use to teach  
25 undergraduates?

# **EXHIBIT DX58**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS



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# Stochastic modeling of atomizing spray in a complex swirl injector using large eddy simulation

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## Abstract

Large-eddy simulation of an atomizing spray issuing from a gas-turbine injector is performed. The filtered Navier–Stokes equations with dynamic subgrid scale model are solved on unstructured grids to compute the swirling turbulent flow through complex passages of the injector. The collocated grid, incompressible flow algorithm on arbitrary shaped unstructured grids developed by Mahesh et al. (*J. Comp. Phys.* 197 (2004) 215–240) is used in this work. A Lagrangian point-particle formulation with a stochastic model for droplet breakup is used for the liquid phase. Following Kolmogorov's concept of viewing solid particle-breakup as a discrete random process, the droplet breakup is considered in the framework of uncorrelated breakup events, independent of the initial droplet size. The size and number density of the newly produced droplets is governed by the Fokker–Planck equation for the evolution of the *pdf* of droplet radii. The parameters of the model are obtained dynamically by relating them to the local Weber number and resolved scale turbulence properties. A hybrid particle-parcel is used to represent the large number of spray droplets. The predictive capability of the LES together with Lagrangian droplet dynamics models to capture the droplet dispersion characteristics, size distributions, and the spray evolution is examined in detail by comparing it with the spray patternation study for the gas-turbine injector. The present approach is computationally efficient and captures the global features of the fragmentary process of liquid atomization in complex configurations.

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**Keywords:** Sprays; LES; Complex geometries; Droplet breakup; Stochastic models

## 1. Introduction

Liquid spray atomization plays a crucial role in analyzing the combustion dynamics in many

propulsion related applications. This has led researchers to focus on modeling of droplet formation in numerical investigations of chemically reacting flows with sprays. In the traditional approach for spray computation, the Eulerian equations for gaseous phase are solved along with a Lagrangian model for droplet transport with two-way coupling of mass, momentum, and

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energy exchange between the two phases [1]. The standard approach is to first perform spray patterning studies for the injector used in combustion chambers and measure the size distributions at various cross-sections from the injector. These distributions are then used as an *input* to a numerical simulation which then computes the secondary atomization of the injected droplets. The secondary atomization is typically modeled by standard deterministic breakup models based on Taylor Analogy Breakup (TAB) [2], or wave [3] models. However, this requires performance of experimental tests for any new injector design which can be very costly.

Development of numerical approaches for direct simulations of the primary atomization of a liquid jet or sheet is necessary. However, such approaches also require significant computational effort. Such numerical schemes capture the complex interactions and instabilities near the gas–liquid interface, formation of ligaments and their disintegration into droplets. Considerable advances have been made in this area [4–6]. The predictive capability of such schemes may be strongly influenced by the grid resolutions used and capabilities for realistic injector geometries are still under development.

Majority of spray systems in propulsion applications involve complex geometries and highly unsteady, turbulent flows near the injector. The numerical models for spray calculations should be able to accurately represent droplet deformation, breakup, collision/coalescence, and dispersion due to turbulence. Simulations involving comprehensive modeling of these phenomena are rare. Engineering prediction of such flows relies predominantly on the Reynolds-averaged Navier–Stokes equations (RANS) [7,8]. However, the large-eddy simulation (LES) technique has been convincingly shown to be superior to RANS in accurately predicting turbulent mixing in simple [9], and realistic [10–12] combustor geometries. It was shown that LES captures the gas-phase flow physics accurately in swirling, separated flows commonly observed in propulsion systems. Recently, Apte et al. [13] have shown good predictive capability of LES in swirling, particle-laden coaxial combustors. The particle-dispersion characteristics were well captured by the Eulerian–Lagrangian formulation.

In this work, LES together with a stochastic subgrid model for droplet atomization is used for simulation of spray evolution in a real gas-turbine injector geometry. Modeling of the complexities of the atomization process is based on a stochastic approach. Here, the details of the ligament formation, liquid sheet/jet breakup in the near injector region are not computed in detail, but their global features are modeled in a statistical sense. Following Kolmogorov's concept of viewing solid particle-breakup as a discrete

random process [14], atomization of liquid drops at high relative liquid-to-gas velocity is considered in the framework of uncorrelated breakup events, independent of the initial droplet size. Gorokhovski and Saveliev [15] reformulated Kolmogorov's discrete model of breakup in the form of a differential Fokker–Planck equation for the *pdf* of droplet radii. The probability to break each parent drop into a certain number of parts is assumed independent of the parent-drop size. Using central limit theorem, it was pointed out that such a general assumption leads to a log-normal distribution of particle size in the long-time limit. This approach was further extended in the context of large-eddy simulations of the gas-phase by Apte et al. [16] and validated for spray evolution in simplified diesel engine configuration.

In this work, the stochastic breakup model is applied to simulate a spray evolution from a realistic pressure-swirl injector to evaluate the predictive capability of the model together with the LES framework. As the first step, cold flow simulation with stochastic model for secondary atomization is performed. This study thus isolates the problem of liquid atomization in pressure-swirl injectors typically used in gas-turbine engines and serves as a systematic validation study for multiphysics, reacting flow simulations in realistic combustors [12].

In subsequent sections, the mathematical formulations for the large-eddy simulation of the gaseous-phase and subgrid modeling of the liquid phase are summarized. Next, the stochastic model for liquid drop atomization is discussed together with a hybrid particle-parcel algorithm, based on the original parcels approach proposed by O'Rourke and Bracco [17], for spray simulations. The numerical approach is then applied to compute unsteady, swirling flows in a complex injector geometry and the results are compared with available experimental data on spray patterning studies.

## 2. Mathematical formulation

The governing equations used for the gaseous and droplet phases are described briefly. The droplets are treated as point-sources and influence the gas-phase only through momentum-exchange terms [13].

### 2.1. Gas-phase equations

The three-dimensional, incompressible, filtered Navier–Stokes equations are solved on unstructured grids with arbitrary elements. These equations are written as

$$\frac{\partial \bar{u}_i}{\partial t} + \frac{\partial \bar{u}_i \bar{u}_j}{\partial x_j} = -\frac{\partial \phi}{\partial x_i} + \frac{1}{Re_{ref}} \frac{\partial^2 \bar{u}_i}{\partial x_j \partial x_j} - \frac{\partial q_{ij}}{\partial x_j} + \bar{S}_i, \quad (1)$$

where  $q_{ij}$  denotes the anisotropic part of the sub-grid-scale stress tensor,  $\bar{u}_i \bar{u}_j - \bar{u}_i \bar{u}_j$ , and the over-bar indicates filtered variables. The dynamic Smagorinsky model is used for  $q_{ij}$  [18]. Equation (1) is non-dimensionalized by the reference length, velocity, and density scales,  $L_{\text{ref}}, U_{\text{ref}}, \rho_{\text{ref}}$ , respectively. The reference Reynolds number is defined as  $Re_{\text{ref}} = \rho_{\text{ref}} L_{\text{ref}} U_{\text{ref}} / \mu_{\text{ref}}$ . The source-term  $\bar{S}_i$  in the momentum-equations represent the ‘two-way’ coupling between the gas and particle-phases and is given by

$$\bar{S}_i = - \sum_k \mathcal{G}_\sigma(\mathbf{x}, \mathbf{x}_p) \frac{\rho_p^k}{\rho_{\text{ref}}} V_p^k \frac{du_{pi}^k}{dt}, \quad (2)$$

where the subscript  $p$  stands for the droplet phase. The  $\sum_k$  is over all droplets in a computational control volume. The function  $\mathcal{G}_\sigma$  is a conservative interpolation operator with the constraint  $\int_{V_{cv}} \mathcal{G}_\sigma(\mathbf{x}, \mathbf{x}_p) dV = 1$  [13], where  $V_{cv}$  is the volume of the grid cell and  $V_p^k$  is the volume of the  $k^{\text{th}}$  droplet.

## 2.2. Liquid-phase equations

Droplet dynamics are simulated using a Lagrangian point-particle model. It is assumed that (1) the density of the droplets is much greater than that of the carrier fluid, (2) the droplets are dispersed, (3) the droplets are much smaller than the LES filter width, (4) droplet deformation effects are small, and (5) motion due to shear is negligible. Under these assumptions, the Lagrangian equations governing the droplet motions become [19]

$$\frac{d\mathbf{x}_p}{dt} = \mathbf{u}_p; \quad \frac{d\mathbf{u}_p}{dt} = \frac{1}{\tau_p} (\mathbf{u}_{g,p} - \mathbf{u}_p) + \left(1 - \frac{\rho_g}{\rho_p}\right) \mathbf{g}, \quad (3)$$

where  $\mathbf{x}_p$  is the position of the droplet centroid,  $\mathbf{u}_p$  denotes the droplet velocity,  $\mathbf{u}_{g,p}$  the gas-phase velocities interpolated to the droplet location,  $\rho_p$  and  $\rho_g$  are the droplet and gas-phase densities, and  $\mathbf{g}$  is the gravitational acceleration. The droplet relaxation time scale ( $\tau_p$ ) is given as [19]

$$\tau_p = \frac{\rho_p d_p^2}{18\mu_g} \frac{1}{1 + aRe_p^b}, \quad (4)$$

where  $d_p$  is the diameter and  $Re_p = \rho_g d_p |\mathbf{u}_{g,p} - \mathbf{u}_p| / \mu_g$  is the droplet Reynolds number.

The above correlation is valid for  $Re_p \leq 800$ . The constants  $a = 0.15, b = 0.687$  yield the drag within 5% from the standard drag curve. Note that some of the above assumptions for the point-particle approach are not valid very close to the injector. The droplets may undergo deformation [20], collision, and coalescence. However, as a first step these effects are not considered and further investigations are needed to evaluate their influence.

## 2.3. Stochastic modeling of droplet breakup

As the physics of primary and secondary atomization are not well understood even in simple and canonical flow configurations, a heuristic approach based on stochastic modeling is followed in order to reduce the number of tuning parameters in an atomization model. A stochastic breakup model capable of generating a broad range of droplet sizes at high Weber numbers has been developed [6,15,16]. In this model, the characteristic radius of droplets is assumed to be a time-dependent stochastic variable with a given initial size-distribution. For very large Weber numbers, there is experimental evidence indicating the fractal nature of atomization process [21,22] wherein large droplets can directly disintegrate into tiny droplets. The stochastic nature of this process is modeled by the present approach. The breakup of parent drops into secondary droplets is viewed as the temporal and spatial evolution of this distribution function around the parent-droplet size according to the Fokker–Planck (FP) differential equation

$$\frac{\partial T(x, t)}{\partial t} + v(\xi) \frac{\partial T(x, t)}{\partial x} = \frac{1}{2} v(\xi^2) \frac{\partial^2 T(x, t)}{\partial x^2}, \quad (5)$$

where the breakup frequency ( $v$ ) and time ( $t$ ) are introduced. The moments  $\langle \xi \rangle = \int_{-\infty}^0 \xi S(\xi) d\xi$  and  $\langle \xi^2 \rangle = \int_{-\infty}^0 \xi^2 S(\xi) d\xi$  are the two parameters of the model that need closure. Here,  $T(x, t)$  is the distribution function for  $x = \ln(r)$ , and  $r$  is the droplet radius. Breakup occurs when  $t > t_{bu} = 1/v$  and  $r > r_{cr}$ , the critical radius of the droplet. Following the arguments of scale similarity analogous to the turbulence cascade behavior at large Reynolds numbers, Gorokhovski and Saviliev [15] looked at the long-time behavior of the droplet breakup. They showed that the initial delta-function for the logarithm of radius of the  $j^{\text{th}}$  primary droplet evolves into a steady state distribution that is a solution to the Fokker–Planck equation [15,16]

$$T_j(x, t + 1) = \frac{1}{2} \left[ 1 + \text{erf} \left( \frac{x - x_j - \langle \xi \rangle}{\sqrt{2\langle \xi^2 \rangle}} \right) \right]. \quad (6)$$

This long time behavior of the distribution is characterized by the dominant mechanism of breakup. Improvements to the model, wherein presence of a liquid core near the injector is taken into account [23], have been proposed, however, in the present work an initial dirac-delta function is assumed at the injector surface.

The value of the breakup frequency and the critical radius of breakup are obtained by the balance between the aerodynamic and surface tension forces. The critical (or maximum stable) radius for breakup is then given as

$r_{cr} = We_{cr} \sigma / (\rho_g u_{r,j}^2)$  where  $|u_{r,j}|$  is the relative velocity between the gas and droplet,  $\sigma$  the surface tension coefficient,  $We_{cr}$  the critical Weber number, which is assumed to be on the order of six over a wide range of Ohnesorge numbers. For highly turbulent flows, however, the instantaneous value of Kolmogorov scale ( $\eta$ ) is often less than the droplet size and the entire spectrum of turbulent kinetic energy can contribute to the stretching and disintegration of the droplet. In this case, the critical radius should be obtained as a balance between the capillary forces and turbulent kinetic energy supplied to the liquid droplet. Accordingly, the relative droplet-to-gas velocity is estimated from the mean viscous dissipation and Stokes time scale ( $\tau_{st}$ ) as  $|u_{r,j}| \approx \epsilon \tau_{st}$  [24]. Using this relative velocity, the critical radius of breakup becomes

$$r_{cr} = \left( \frac{9}{2} \frac{We_{cr} \sigma v_{lam}}{\epsilon \rho_l} \right)^{1/3}, \quad (7)$$

where  $v_{lam}$  is the kinematic viscosity,  $\rho_l$  is the liquid density, and  $\epsilon$  is the viscous dissipation rate. In the present LES study, the viscous dissipation can be obtained dynamically from the resolved scale energy flux. The breakup frequency is obtained following the analogy with expressions used for aerodynamic breakup and utilizing the relative velocity ( $|u_{r,j}|$ ) from above

$$t_{bu} = B \sqrt{\frac{\rho_l}{\rho_g}} \frac{r_j}{|u_{r,j}|}, \quad (8)$$

where  $r_j$  is the radius of parent drop and  $B = \sqrt{1/3}$  [2,25].

If the breakup criterion ( $t > t_{bu}$  and  $r > r_{cr}$ ) for a parent droplet is satisfied, secondary droplets are sampled from the analytical solution (Eq. 6) corresponding to the breakup time-scale. The parameters encountered in the FP equation ( $\langle \xi \rangle$  and  $\langle \xi^2 \rangle$ ) are computed by relating them to the local Weber number for the parent drop, thereby accounting for the capillary forces and turbulent properties. Apte et al. [16] assumed that in the intermediate range of scales between the parent drop element (large Weber number) and the maximum stable droplet (critical Weber number) there exists no preferred length scale, following the fractal nature of atomizing spray [22]. This closely resembles the inertial range of the energy cascade process in homogeneous turbulence at high Reynolds numbers. Analogously, assuming  $u_{r,j}^3/r_j = u_{r,cr}^3/r_{cr}$ , one obtains

$$\frac{r_{cr}}{r_j} = \left( \frac{We_{cr}}{We_j} \right)^{3/5} \Rightarrow \langle \ln \alpha \rangle \equiv \langle \xi \rangle = K \ln \left( \frac{We_{cr}}{We_j} \right), \quad (9)$$

where  $u_{r,cr}$  is the relative velocity at which disruptive forces are balanced by capillary forces (similar to turbulent velocity scale of the smallest

eddies) and the constant  $K$  is of order unity ( $\sim 0.6$ ). This gives expression for one of the parameters  $\langle \xi \rangle$ .

Furthermore, from the Einstein's theory of Brownian motion, the diffusion coefficient in the Fokker–Planck equation is known to be the energy of Brownian particles multiplied by their mobility. The drift velocity is presented in the form of drag force times the mobility. The ratio of diffusion to drift velocity is given by the ratio of energy to drag force. In the breakup process, the energy in Einstein's theory is associated with the disruptive energy while the force is associated with the capillary force on the droplet. Normalized by the length scale of the parent drop, this ratio is characterized by the Weber number. Considering the Fokker–Planck equation (Eq. 5), the diffusion to drift velocity ratio is scaled by  $-\langle \xi^2 \rangle / \langle \xi \rangle$ . Then it is assumed that

$$-\frac{\langle \xi \rangle}{\langle \xi^2 \rangle} \equiv -\frac{\langle \ln \alpha \rangle}{\langle \ln^2 \alpha \rangle} = We_j^{-1}. \quad (10)$$

This relationship gives the maximum dispersion of newly produced droplet sizes. Thus, both the parameters in the Fokker–Planck equation are obtained dynamically by computing the local value of  $We_j$ , and knowing  $We_{cr}$ .

Once new droplets are created, the product droplet velocity is computed by adding a factor  $\mathbf{w}_{bu}$  to the primary drop velocity. This additional velocity is randomly distributed in a plane normal to the relative velocity vector between the gas-phase and parent drop, and the magnitude is determined by the radius of the parent drop and the breakup frequency,  $|\mathbf{w}_{bu}| = rv$ . This modification of newly formed droplets follows the physical picture of parent droplets being torn apart by aerodynamic forces giving momentum to the newly formed droplets in the direction normal to the relative velocity between the gas-phase and parent drops [2].

As new droplets are formed, parent droplets are destroyed and Lagrangian tracking in the physical space is continued till further breakup events. In the present work, the liquid spray is injected at atmospheric pressure and temperatures. The rates of evaporation are very small and droplet evaporation is neglected.

#### 2.4. Subgrid scale modeling

In LES of droplet-laden flows, the droplets are presumed to be *subgrid*, and the droplet-size is smaller than the filter-width used. The gas-phase velocity field required in Eq. (3) is the total (unfiltered) velocity, however, only the filtered velocity field is computed in Eq. (1). The direct effect of unresolved velocity fluctuations on droplet trajectories depends on the droplet relaxation time-scale, and the subgrid kinetic energy. Considerable progress has been

made in reconstructing the unfiltered velocity field by modeling the subgrid scale effects on droplet dispersion. Bellan [26] provides a good review on this topic in the context of spray modeling. Majority of the works related to subgrid scale effects on droplet motion have been performed for dilute loadings, wherein the droplets are either assumed smaller than the LES filter size or the Kolmogorov length scale. For dense spray systems, droplet dispersion and droplet interactions with subgrid scale turbulence are not well understood. In addition, in realistic configurations the droplet sizes very close to the injector can be on the order of the grid size used for LES computations.

Recently, Pozorski and Apte [27] performed a systematic study of the direct effect of subgrid scale velocity on particle motion for forced isotropic turbulence. It was shown that, in poorly resolved regions, where the subgrid kinetic energy is more than 30%, the effect on droplet motion is more pronounced. A stochastic model reconstructing the subgrid-scale velocity in a statistical sense was developed [27]. However, in well resolved regions, where the amount of energy in the subgrid scales is small, this direct effect was not strong. In the present work, the direct effect of subgrid scale velocity on the droplet motion is neglected. However, note that the droplets *do feel* the subgrid scales through the subgrid model that affects the resolved velocity field. For well-resolved LES of swirling, separated flows with the subgrid scale energy content much smaller than the resolved scales, the direct effect was shown to be small [13].

### 3. Numerical method

The computational approach is based on a co-located, finite-volume, energy-conserving numerical scheme on unstructured grids [10] and solves the incompressible Navier–Stokes equations. The velocity and pressure are stored at the centroids of the control volumes. The cell-centered velocities are advanced in a predictor step such that the kinetic energy is conserved. The predicted velocities are interpolated to the faces and then projected. Projection yields the pressure potential at the cell-centers, and its gradient is used to correct the cell and face-normal velocities. A novel discretization scheme for the pressure gradient was developed by Mahesh et al. [10] to provide robustness *without numerical dissipation* on grids with rapidly varying elements. This algorithm was found to be imperative to perform LES at high Reynolds numbers in realistic combustor geometries and is essential for the present configuration. This formulation has been shown to provide very good results for both simple and complex geometries [10–12].

In addition, for two-phase flows the particle centroids are tracked using the Lagrangian framework.

The particle equations are integrated using third-order Runge–Kutta schemes. Owing to the disparities in the flowfield time-scale and the droplet relaxation time ( $\tau_p$ ) subcycling of the droplet equations may become necessary. After obtaining the new droplet positions, the droplets are relocated, droplets that cross interprocessor boundaries are duly transferred, boundary conditions on droplets crossing boundaries are applied, source terms in the gas-phase equation are computed, and the computation is further advanced. Solving these Lagrangian equations thus requires addressing the following key issues: (i) efficient search for locations of droplets on an unstructured grid, (ii) interpolation of gas-phase properties to the droplet location for arbitrarily shaped control volumes, (iii) interprocessor droplet transfer. An efficient Lagrangian framework was developed which allows tracking millions of droplet trajectories on unstructured grids [13,16].

#### 3.1. Hybrid droplet-parcel algorithm for spray computations

Performing spray breakup computations using Lagrangian tracking of each individual droplet gives rise to a large number of droplets ( $\approx 20$ –50 million) in localized regions very close to the injector. Simulating all droplet trajectories gives severe load-imbalance due to presence of droplets on only a few processors. On the other hand, correct representation of the fuel vapor distribution obtained from droplet evaporation is necessary to capture the dynamics of spray flames. In their pioneering work, O’Rourke and Bracco [17] used a ‘discrete-parcel model’ to represent the spray drops. A parcel or computational particle represents a group of droplets,  $N_{\text{par}}$ , with similar characteristics (diameter, velocity, and temperature). Typically, the number of computational parcels tracked influences the spray statistics predicted by a simulation.

The original work of O’Rourke and co-workers [2,17] inject parcels from the injector, resulting in much fewer number of tracked computational particles. In this work, the parcels model is further extended to a hybrid particle-parcel scheme [16]. The basic idea behind the hybrid-approach is as follows. At every time step, droplets of the size of the spray nozzle are injected based on the fuel mass flow rate. New droplets added to the computational domain are pure drops ( $N_{\text{par}} = 1$ ). These drops are tracked by Lagrangian particle tracking and undergo breakup according to the stochastic model creating new droplets of smaller size. As the local droplet number density exceeds a prescribed threshold, all droplets in that control volume are collected and grouped into bins corresponding to their size. The droplets in bins are then used to form a parcel by conserving mass. Other properties of the parcel are obtained by

mass-weighted averaging from individual droplets in the bin. The number of parcels created would depend on the number of bins and the threshold value used to sample them. A parcel thus created then undergoes breakup according to the above stochastic sub-grid model, however, does not create new parcels. On the other hand,  $N_{\text{par}}$  is increased and the diameter is decreased by mass-conservation.

This strategy effectively reduces the total number of computational particles in the domain. Regions of low number densities are captured by individual droplet trajectories, giving a more accurate spray representation.

4. Computational details

Figure 1 shows a schematic of the computational domain used for the spray patterning study of a realistic Pratt and Whitney injector. The experimental data set [28] (R. McKinney, R.K. Madabhushi, S. Syed, private communication, 2002) was obtained by mounting the actual injector in a cylindrical plenum through which gas with prescribed mass-flow rate was injected. Figure 1b shows a cut through the symmetry plane ( $Z/L_{\text{ref}} = 0$ ) of the computational domain along with the mesh and boundary conditions used. For this case, 3.2M grid points are used with high resolution near the injector. The grid elements are a combination of tetrahedra, prisms, wedges, and hexahedra to represent complex geometric passages inside the injector. Grid refinement study for LES of single phase flow has been performed for different cases in complex configurations [10,11]. The grid resolution for the present case was decided based on these validation studies.

Air from the inlet plenum goes through the central core, guide, and outer swirlers to create

highly unsteady multiple swirling jets. The domain decomposition is based on the optimal performance of the Eulerian gas-phase solver on 96 processors. Brankovic et al. [28] provide details of the experimental measurement techniques and inflow conditions for a lower pressure drop across the fuel nozzle. The inflow conditions in the present study are appropriately scaled to a higher pressure drop providing the air mass flow rate of 0.02687 kg/s. The flow Reynolds number based on the inlet conditions is 14,960. A uniform mean inflow velocity was specified at the inlet without any turbulent fluctuations. In the present case, the downstream cylindrical plenum is open to atmosphere. The air jet coming out of the nozzle thus entrains air from the surrounding. Entrained flow along the surface of the downstream plenum was modeled as a radially inward velocity along the entire plenum surface. The experimental data profiles at different cross-sections were integrated at each station to obtain the total flow rate at those locations. Knowing the net inflow rate, the entrained mass at each of the entrainment boundaries was estimated and assigned to the calculation. This modeling approach for entrained flow is subject to experimental verification, however, was shown to have little impact on the predicted flowfield [28]. No-slip conditions are specified on the wall. Convective boundary conditions are applied at the exit section by conserving the global mass flow rate through the computational domain. and experimentally measured radial entrainment rate is applied on the cylindrical surface of the computational domain downstream of the injector.

Liquid fuel is injected through the filer surface which forms an annular ring near the outer swirler. In the symmetry plane this is indicated by two points on the edge of the annular ring. The ratio of the liquid to air mass flow rates at the inlet is fixed at 0.648. The liquid film at the fil-

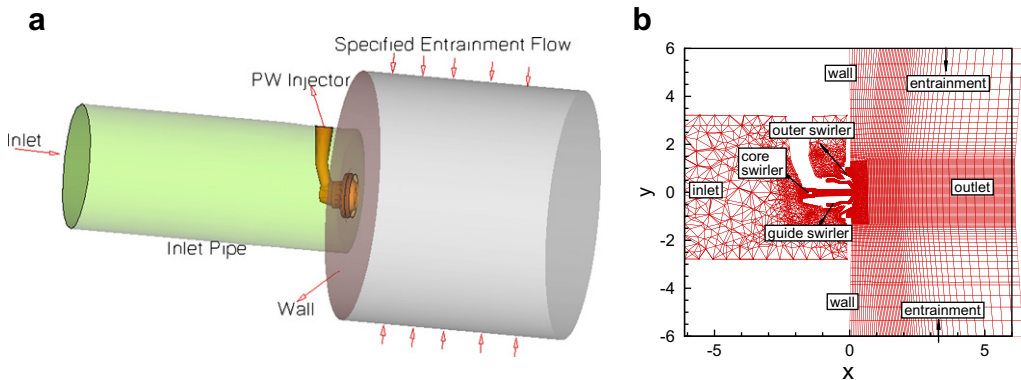


Fig. 1. The computational domain: (a) schematic of entire region and (b) unstructured grid near the injector in the symmetry plane.

mer surface is approximated by injecting uniform size large drops of the size of the annular ring thickness. These drops are convected downstream by the swirling air and undergo breakup according to the stochastic model. The velocity of each droplet is specified based on the velocity of the liquid film. A large number of droplets are created in the vicinity of the injector due to breakup. The location of droplet injection around the annular ring is chosen using uniform random distribution. This discrete representation of the film near the injector surface may not represent the physics of ligament formation and film breakup. However, the statistical nature of droplet formation further away from the injector is of interest in the present study and is well captured by the stochastic model together with LES of the air flow.

With the hybrid approach, the total number of computational particles tracked at stationary state is around 3.5 M and includes around 150,000 parcels. Together these represent approximately 13 M droplets.

The computations were performed on the IBM cluster at the San Diego Supercomputing center.

## 5. Results and discussion

Figure 2a and b shows the instantaneous snapshots of the axial velocity contours in the  $Z/L_{\text{ref}} = 0$  symmetry plane and in cross-section  $X/L_{\text{ref}} = 1.1$ . Figure 2c and d shows the corresponding snapshots for spray droplets (white dots). The swirling air jet from the core swirler enters the dump region and forms a recirculation zone. Jets from guide and outer swirlers interact with the core flow. The swirling air jets entering the sudden expansion region create radially spreading conical jets with a large recirculation region just downstream of the injector. A complex vortex break down phenomenon is observed and its accurate prediction is necessary to correctly represent the injector flow. The swirl strength decays further away from the injector due to viscous dissipation. The scatter plot of the spray droplets show dense spray regimes close to the injector which become dilute further away. The parent droplets are injected at the edge of the annular ring. These droplets are carried by the swirling flow and form a conical spray. The concentration of the spray droplets is high on the edge of the recirculation region. The strong relative motion between the large inertial droplets near the injector and the fluid flow leads to breakup and generation of smaller droplets. The droplets spread radially outward and swirl around the injector axis as they move downstream.

Figure 3a and b compares the LES predictions to the available experimental data of radial variations of mean axial and swirl velocity at different axial locations. The numerical results are

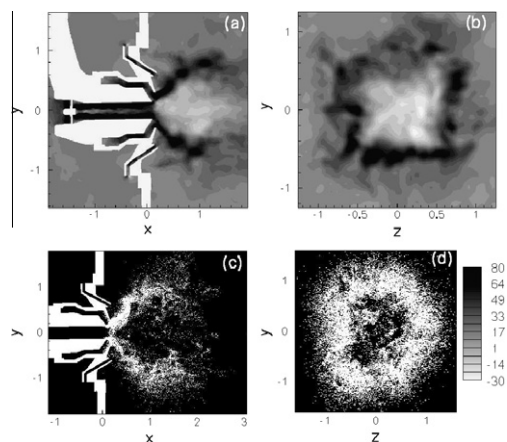


Fig. 2. Instantaneous snapshots of near-injector axial velocity field and spray droplets: (a) axial velocity in  $Z/L_{\text{ref}} = 0$ , (b) axial velocity in  $X/L_{\text{ref}} = 1.1$ , (c) spray droplets in  $Z/L_{\text{ref}} = 0$ , and (d) spray droplets in  $X/L_{\text{ref}} = 1.1$ . Also shown is the color scale for normalized axial velocity.

azimuthally averaged. The predictions from our simulation are in close agreement with the experimental data (R. McKinney, R.K. Madabhushi, S. Syed, private communication, 2002). The size and evolution of the recirculation region is well captured as indicated by the axial velocity predictions. The swirl strength decays downstream of the injector. Small disagreement at  $X/L_{\text{ref}} = 2.1$  is partly related to the coarse grid resolution used away from the injector. It should be noted that the amount of swirl generator by the injectors determines the size of the recirculation zone. Good agreement of the axial and swirl velocities indicate that LES with dynamic *sgs* model can capture the vortex break-down phenomenon accurately in complex geometries. Also shown are the corresponding predictions using the standard  $k-\epsilon$  model on the present grid. The unsteady RANS solutions are in agreement with the LES and experimental data very close to the injector, however, degrade rapidly further away, showing limitations of the turbulence model. RANS predictions of the flow through the same injector at different conditions [28] show similar trends. Improved predictions using advanced RANS models can be obtained, however, the superiority of LES is clearly demonstrated. Any artificial dissipation or inaccurate numerics gives faster decay of the swirl velocities and incorrect size of the recirculation region, further emphasizing the importance of *non-dissipative* numerical schemes for LES.

Figure 4a and b compares the radial variation of liquid mass-flowrates using LES and the stochastic model to the experimental data at two different cross-sections. The flow rates are presented

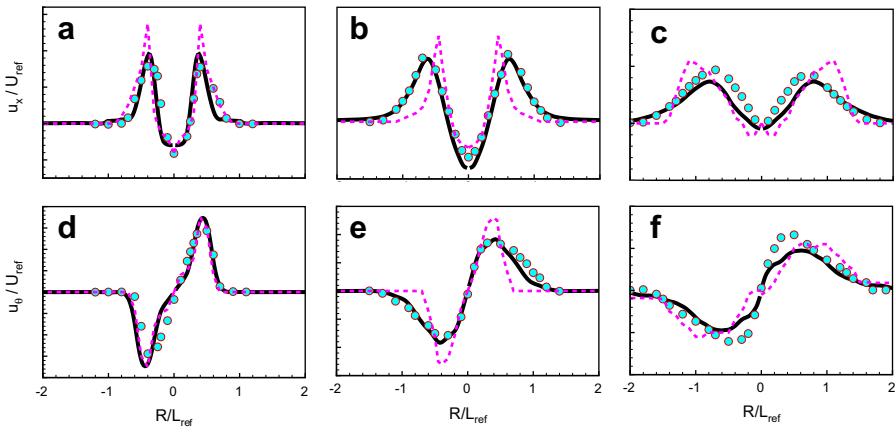


Fig. 3. Radial variation of normalized mean axial and swirl velocity at different axial locations,  $\circ$  experimental data (R. McKinney, R.K. Madabhushi, S. Syed, private communication, 2002), — LES, - - - RANS: (a and d)  $X/L_{ref} = 0.4$ , (b and e)  $X/L_{ref} = 1.1$ , (c and f)  $X/L_{ref} = 2.1$ .

as the ratio of the effective to the integrated flow rate. The effective flow rate is defined as the flow rate the patternator would record if the fuel flux was uniform at the local value. This normalization inherently carries the ratio of the total cross-sectional area to the area of the local patternator holes. The LES results are generally in good agreement with the experiments. Average droplet sizes at two axial location from the injector wall have been measured using the Malvern line of sight technique (R. McKinney, R.K. Madabhushi, S. Syed, private communication, 2002). The Sauter mean diameters averaged over the cross-section at these two axial locations are predicted within 5% of the experimental values.

Figure 5a and b compares the mass-based size-distribution function compared with the experimental data at two different cross-sections from the injector. It is observed that the predicted distribution functions agree with experimental observations for large-size droplets. However, the

simulations predict larger mass of small size droplets compared with the experimental data. This is attributed to the lack of collision/coalescence models in the present simulation. Also, small size droplets can easily evaporate even at low temperatures and the present simulations do not consider this effect. In addition, the initial droplet size at the injector nozzle is assumed to be a constant, whereas it may vary depending on the local conditions governing primary atomization. Models taking into account the presence of a liquid core near the injector can be incorporated to better capture the recirculation regions. A dirac-delta function was used to inject large drops from the injector surface and a better representation of these initial conditions can improve the predictions [23]. Further improvements to the model can also be obtained by modeling the primary breakup regime very close to the injector. An investigation with inclusion of collision models as well as using a size distribution at the inlet should be performed in

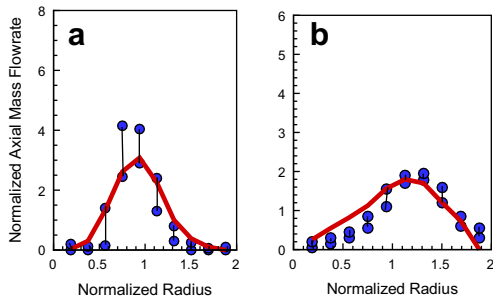


Fig. 4. Comparison of radial variation of normalized liquid axial mass flux at two axial locations,  $\circ$  —  $\circ$  experimental error bar (R. McKinney, R.K. Madabhushi, S. Syed, private communication, 2002), — LES: (a)  $X/L_{ref} = 1.1$  and (b)  $X/L_{ref} = 2.1$ .

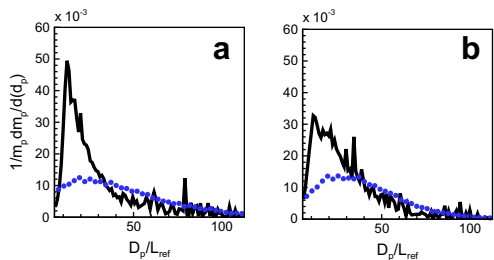


Fig. 5. Comparison of normalized droplet mass-distribution at different axial locations,  $\circ$  experiments (R. McKinney, R.K. Madabhushi, S. Syed, private communication, 2002), — LES: (a)  $X/L_{ref} = 1.1$  and (b)  $X/L_{ref} = 2.1$ .

order to investigate uncertainties in model predictions. However, the overall predictions of the LES methodology together with a simple stochastic breakup model of liquid atomization are in good agreement with experiments. The dispersion of droplets in an unsteady turbulent flow is well represented when the flowfield is computed using LES.

## 6. Summary and conclusions

A large-eddy simulation of an atomizing spray issuing from a gas-turbine injector is performed corresponding to the spray patternation study of an injector used in a Pratt and Whitney combustor. The filtered Navier–Stokes equations with dynamic subgrid scale models are solved on unstructured grids to compute the swirling turbulent flow through complex passages of the injector. A Lagrangian point-particle formulation with stochastic models for droplet breakup is used for the liquid phase. The atomization process is viewed as a discrete random process with uncorrelated breakup events, independent of the initial droplet size. The size and number density of the newly produced droplets is governed by the Fokker–Planck equation for the evolution of the *pdf* of droplet radii. The parameters of the model are obtained dynamically by relating them to the local Weber number and resolved scale turbulence properties. It is assumed that for large Weber numbers there exists no preferred length scale in the intermediate range of scales between the parent drop element and the maximum stable droplet, following the fractal nature of atomizing spray [21,22]. A hybrid particle-parcel approach is used to represent the large number of spray droplets. The swirling, separated regions of the flow in this complex configuration are well predicted by the LES. The droplet mass fluxes and size distributions predicted are within the experimental uncertainties further away from the injector. The present approach, however, overpredicts the number density of small size droplets which can be attributed to the lack of coalescence modeling. In addition, the primary breakup regime very close to the injector was not simulated. Models taking into account the presence of a liquid core near the injector [23] can be incorporated to better capture the recirculation regions. However, with present stochastic approach the droplet dispersion characteristics are well captured. The global features of the fragmentary process of liquid atomization resulting in a conical spray are well represented by the present LES in realistic injector geometry. This stochastic modeling approach has been used to perform full scale simulations of turbulent spray combustion in a real Pratt and Whitney combustion chamber [12].

## Acknowledgments

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# **EXHIBIT DX59**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS

Available online at [www.sciencedirect.com](http://www.sciencedirect.com)

## Journal of Hospital Infection

journal homepage: [www.elsevierhealth.com/journals/jhin](http://www.elsevierhealth.com/journals/jhin)

## LETTER TO THE EDITOR

## Active warming systems to maintain perioperative normothermia in hip replacement surgery

Madam,

In response to Moretti *et al.*'s article 'Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infection?', the National Institutes of Health (NIH) used computational fluid dynamics (CFD) and particle-tracking methodology to assess whether a forced-air patient-warming system increases the risk of nosocomial infections at the surgical wound site.<sup>1</sup> NIH analysed laminar airflow disruption and room airflow patterns to determine the effect of squame impingement from personnel surrounding the operating table as a source of surgical wound infection.

The literature indicates that a forced-air warmer system may disturb the operating room laminar airflow and increase the risk of nosocomial infections. Memarzadeh *et al.* used advanced numerical modelling and empirical data to evaluate the effects of room parameters on minimising surgical site contamination risk from specific particulate sources.<sup>2,3</sup> Their work shows that <1% of particles hitting the surgical site from the anaesthesiologist location are due to the relative dominance of the thermal plume caused by the surgical site.<sup>3</sup>

Using colony-counting methodology to determine settling of squames on the surgical site, Moretti *et al.* concluded that the body-warming system does not pose a risk of nosocomial infections and that the increased bacterial load found after application of a body warming system is comparable to, or lower than, the load present at the time of placement of the patient on the operating table.<sup>1</sup>

Memarzadeh explains that turbulent airflow in a ventilated room transports the squames by both airflow convection and turbulent diffusion. The influence of the squames' motions and temperatures on the fluid flow parameters is negligible because squames are sufficiently light and their volume flow rate is substantially lower than those of the fluid stream. The distributions of air velocities and the turbulent parameters from the CFD simulation output are directly applied to predict the path of the airborne squames in convection and diffusion processes. The particle motion in the air obeys an equation, as described further in our full publication.

The NIH analysis includes heat-generating factors and ventilation factors. The air supply temperature was determined by the average room air temperature (70°F) assuming 15 and 20 air changes per hour (ACH).

NIH made observations with the air warmer on and off compared with two ventilation flow rates. The squames are 25 µm by 3–5 µm thick. Approximately 30 000 total squames were released from the head and arms of the anaesthesiologist location and tracked for

1 h. The number of squames deposited on the patient surface was compared for both scenarios.

Simulation results of flow fields and particle tracking show velocity plots at the vertical plane cutting through the centre of the operating table with 20 ACH for the two scenarios. Flow patterns in both plots are similar except that the downward velocity from ceiling laminar diffuser is slightly less strong with the forced-air warmer operating than when the air warmer is off. Similar flow patterns are observed 1 h after the squames are released from the sources. Since the operating air warmer system adds hot air but also dissipates heat to the region around the bed, the air temperature is apparently higher than when the air warmer is off. The squame plots show that particles are cleaned away from the patient by the airflow from the laminar diffuser no matter if the forced air warmer is on or off. The percentage of squames deposited on the patient was zero both when the forced air warmer was on or off. The percentage of squames vented at the exhausts was 5.58% when the forced air warmer was operating and 5.26% when it was off. The percentage of squames being vented out is low because they stick to the solid surfaces during the 1 h tracking before reaching the return grilles.

NIH concludes that in both scenarios, there is zero percent deposition on the patient for the contaminant sources and the heat generated by the patient provides some protection. Although squames from the anaesthesiologist location move upwards due to thermal plume and away from the surgical site, supply flows largely dictate airflow pattern. When the forced-air warmer is operating, the downward velocity from ceiling laminar diffuser is slightly less strong than when it is off. With same supply air temperature, the air temperature around the surgical table is warmer when the forced-air warmer is operating. Forced-air warmers seem to cause minimal disruption to laminar airflow systems that help protect the surgical site from contaminated particles sourced from surgical staff.

This investigation validates Moretti *et al.*'s conclusion that forced-air warming technology does not increase the risk of surgical wound infection. Further, if the operating room ventilation system is designed properly, contaminating particles from staff around the patient will not impinge on the surgical wound due to 'thermal plume' dynamics.

**Conflict of interest statement**

None declared.

**Funding source**

US National Institutes of Health.

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# **EXHIBIT DX60**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS

1 UNITED STATES DISTRICT COURT  
2 DISTRICT OF MINNESOTA

3 In re: Bair Hugger Forced Air  
4 Warming Products Liability  
5 Litigation

MDL No. 2666

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8 VIDEOTAPED DEPOSITION OF  
9 YADIN DAVID, Ed.D., P.E., C.C.E.  
10 Houston, Texas  
11 Tuesday, August 1, 2017  
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13  
14  
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19 Reported by:  
20 SUSAN PERRY MILLER, RDR, CRR, CRC  
21 JOB NO. 124787  
22  
23  
24  
25

Y. DAVID

that all of those materials are either cited in your report -- I'm sorry, let me separate that out.

Are there materials in that box that are not cited in your report or listed on the materials review list?

A. Everything is listed and cited one way or another.

Q. Okay. I'm going to go through it in a little more detail later, but for now, I just wanted to get that baseline.

Why did you obtain a Bair Hugger unit for purposes of your work in this case?

A. Sure. I wanted to acquaint myself with the product, with the way it is built, with its design, with the way that it is supposed to operate, and with the internal component that have Bair in this case.

Q. Had you ever seen a Bair Hugger device before you ordered the one from eBay that's described in your report?

A. I just want to correct one thing. I did not order myself. I asked counsel to order it for me.

Y. DAVID

Q. Thank you for that correction.

A. And --

Q. Before the device was obtained for purposes of your review that is described in your report, had you ever seen a Bair Hugger device before?

A. I did.

Q. Tell me about that.

A. I have been working for almost three decades in hospitals, and I recalled walking different areas of these hospitals, especially in the late '90s, that I've seen the Bair Hugger product used in patient rooms.

Q. Is that a specific memory of the late '90s as opposed to other time frames?

A. Correct.

Q. Did your profession -- okay. So you saw a Bair Hugger device in use in patient rooms.

What hospital or hospitals?

A. It would be difficult for me to pinpoint specific hospitals. I'll give you a list of a few of them that I worked at at the time that we are discussing here, and those

Y. DAVID

will be the St. Luke's Episcopal Hospital here in Houston and the Texas Children Hospital at the -- here in the Medical Center.

Q. In Houston also?

A. Correct.

Q. Okay. Those were the two hospitals you were working at at the time when you believe you saw a Bair Hugger device?

A. Correct.

Q. What was your responsibility at those two hospitals at that time, in the late 1990s?

A. I was the director of the biomedical engineering department.

Q. What does that mean?

A. That means that I have the responsibility to make sure that medical technology used in these hospitals is selected, installed, maintained, and in service properly.

Q. You said "medical technology." What does that encompass?

A. In general, that will be biomedical devices.

Y. DAVID

Q. Can you give me an example of some biomedical devices?

A. Absolutely. Biomedical devices used for managing and diagnosing patient condition will be bedside monitors that -- looking at patient vital signs. It will be X-ray machines, lasers in surgery. It will be blood-warming devices and laboratory diagnostic instruments.

Q. Is that a complete list?

A. Oh, my God, no.

Q. Okay. Those were examples?

A. I was responsible for about 25,000 devices, biomedical devices, so we probably can spend the day going through the type of biomedical device on these assets.

Q. Would the Bair Hugger device be within the type of devices that you were responsible for?

A. I do not recall.

Q. You don't recall ever making an evaluation or decision about a Bair Hugger device?

A. Correct.

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Q. Would it have been within the category of biomedical devices that you -- would fall within the scope of your job?

A. Depends how it's arrived into that patient's room. If it was intended to be purchased, absolutely it would be my responsibility to review and evaluate. If it was on loan, rent, or brought by a third party, it will not be subjected to my evaluation.

Q. Do you know, at either St. Luke's or Texas Children's Hospital, if the device was purchased or brought in in some other way?

A. No, I do not.

Q. Is that distinction you've made about purchased versus brought in some other way something that would apply at both of the hospitals that you've listed, St. Luke's and Texas Children's?

A. Correct.

Q. Okay. Why do you -- are you saying there's a policy or procedure set out that that's how your responsibilities fall?

A. We did have many policies, and my

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program was very well scripted and structured. There were a flexibility for especially the clinical staff to become aware of new technologies and use or review them on the loan basis or as a donation. That would be not subjected to evaluation.

Q. Did you say "clinical staff"?

A. I did.

Q. I wanted to make sure. At first I thought I heard the word "stuff" but I thought that you must have meant "staff."

A. I apologize for my accent, but I referred to people who were involved with clinical activities.

Q. Thank you. No need to apologize. I just wanted to be sure I understood you.

You're saying there was a policy of flexibility for clinical staff to use instruments that didn't come in through purchasing?

A. Correct.

Q. Was your role as biomedical engineer tied only to purchasing, then, devices purchased?

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A. That's correct. My responsibility was to ensure that recommendations for commitment of hospital financial resources towards medical technology, i.e., biomedical devices, are based on several aspects that include the cost-benefit ratio analysis, risk analysis, and match between product feature and clinical needs, and that separate than trying to educate clinicians about new product or different product than they use.

MS. EATON: Can I just -- I just wanted to read one thing there, I'm sorry.

(Counsel reviewing realtime transcript on the reporter's computer.)

BY MS. EATON:

Q. I'm going to return to that history in a moment.

Had you ever -- but for now I want to return to the device that you evaluated for purposes of your work in this case.

Had you ever touched or used a Bair Hugger device before the one you obtained for your evaluation here?

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A. Besides the one that I operated?

Q. I'm sorry, my question may not have been clear. For purposes of your work in this lawsuit and preparing the report that you prepared, did you obtain and review and operate a Bair Hugger device?

A. Correct.

Q. Other than -- how many Bair Hugger devices?

A. One.

Q. Other than that one, before you obtained that one, have you ever operated a Bair Hugger device before?

A. Not that I recall.

Q. Have you ever touched one before, in any way?

A. I cannot ascertain that. That does not ring a bell.

Q. You said you had a memory of having seen them in hospitals. Did you -- what is the -- can you tell me more about that memory? What do you recall?

A. No, I cannot.

Q. You recall having seen them and

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Y. DAVID

that's it?

A. Correct.

Q. Okay. Do you recall having any sense, at the time you saw them, for why they were in an operating room?

A. I mentioned it was patient room. I didn't say operating room.

Q. Oh, I'm sorry. Can you please clarify for me, where did you see one?

A. I don't recall it. I don't believe I was walking the operating room.

Q. What do you mean by "patient room"?

A. An area where a patient is being observed on one of the general floors.

Q. Is this something before or after surgery or not in connection with surgery at all?

A. I have no recollection of that.

Q. Do you have any recollection of the specific hardware -- in other words, what model it would be, how large it was, how it compares to the one that you obtained for use in this case?

A. No.

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Y. DAVID

Q. Is this a specific memory of having seen it one time, or do you believe you saw a Bair Hugger device more than one time?

A. We are talking about something that is about 20 years ago or more, so I cannot differentiate if it's one or two times. Definitely not something that would be frequent.

Q. So with the clarification that you saw it in a patient room, do you recall having any understanding at the time you saw it about why it was in the patient room?

A. No.

Q. Do you recall any discussion, ever, during your work at a hospital, about Bair Hugger devices and their use?

A. No.

Q. And I shouldn't have added those last two words, because I meant it to be a very broad question. Do you recall any conversation during your time working in any hospital about Bair Hugger devices?

A. No.

Q. Were you responsible for making any

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evaluation or assessment about disposables that are used with medical technology?

A. Yes, I did.

Q. Did you ever make any evaluation or assessment about blankets used with the Bair Hugger device?

A. I don't believe so.

Q. Did every piece of medical technology that came into an operating room become subject to an evaluation by your department, if it was purchased?

A. My ego says answer that as a positive yes so I can reflect on a very good program. I would say the first time a type of device is acquisitioned, probably it will be evaluated. But if the same device is being purchased years later and again and again, it would not.

Q. Did you start the question -- I'm sorry. Did you start your answer by saying your ego would say yes because it was a good program?

A. Yes.

Q. Okay. Meaning, in your mind, if

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you had a good program, you would want to have looked at all the devices that were being purchased?

MR. BANKSTON: Object to the form.  
BY MS. EATON:

Q. Is that right?

A. The point to bring to this question is that the process in the hospital is so complex that there may be avenues that are not main street but on the perimeter the device is coming in through some kind of special relationship with a vendor, and I would not have the benefit of passing evaluation or judgment on that.

Give an example, a blood analyzer in the lab may have been purchased by buying the agents that are used in the blood-drawing process, the chemical agent. So as long as the hospital buys those chemical agents, the product is given to the hospital and there is no evaluation involvement because there's no purchasing of capital item. It's like the Schick blade; you get the holder if you buy the razor or something like that.

Y. DAVID

Q. Within the terms of the programs at -- I'm sorry. Were you responsible for evaluating products at both Texas Children's and St. Luke's at certain times?

A. At certain times, correct.

Q. Within the program as you understand it at those hospitals, would the purchase of Bair Hugger blankets have brought the Bair Hugger device up for review by you, or not?

A. Now I'm hypothesizing with you about my response, because if you are telling me that there is requisition to buy a blanket, it sounds to me like the product is already in the hospital, so just add another accessory would not be subjected to evaluation.

Q. Do you know if Bair Hugger devices were purchased by either Texas Children's or St. Luke's Hospitals?

A. At the time that I was there, no, I don't know.

Q. Do you know if blankets were purchased?

A. No.

Y. DAVID

Q. You don't recall evaluating a Bair Hugger device -- and I apologize if I already asked you this. Do you recall ever evaluating the blankets?

A. I do not.

Q. Had you ever disassembled a Bair Hugger device before the work you did for this case?

A. No, I did not.

Q. And do you have any memory about the way the Bair Hugger device or devices you recall having seen in the past were being operated?

A. No, I do not.

Q. Why did you choose to examine a previously used Bair Hugger device for your work in this case?

A. Actually, this is a very good question. Because usually if you would like to review the device performance, especially in a clinical setting, you would like to have a new product that is fully capable to deliver all these features.

On the other hand, my goal

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specifically was to see device operation and the inside of the device after it was used in the field. So on purposely, I wanted to get a device that had some field experience with it.

Q. Why?

A. Because it gives me a view of what the device's capability to sustain its features in the field after it's been used for a period of hours. For example -- and I pointed that in my report -- is that I looked at the four feet on the bottom of the device and gave -- and realized that this device was used much on the floor because you could see the wear and tear on those four points at the base of the device.

So a device sitting on the floor has different performance on its enclosure than a device that would be up on the shelf or on an IV pole.

Q. What do you mean, it has a difference in the enclosure?

A. The performance of the characteristics of the physical enclosure, the box that covered the whole internal operation

Y. DAVID

and the components inside are subjected to specific wear and tear from floor, such as operating floors and recovery room floors.

Q. How does the floor and whether the device is placed on the floor or not impact the inside of the device, to your understanding?

A. There is a significant difference. A device that is placed on the floor is in closer proximity to an area that is not clean, that has higher concentration of pathogens, and that have more -- a higher percentage of relative humidity around the intake of the device. This gives rise to additional contamination of pathogens that the device can harbor.

Q. Okay. Did you examine a device that had been used and was not placed on the floor to see if the inside of the device looked any different?

A. Once again, I don't know where the device was used, but it's my observation that the bottom part of the device, the four feet, were subjected to significant wear and tear;

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Y. DAVID

Q. In your professional capacity outside of litigation, have you ever had reason to review an inspection report from the agency?

A. Outside litigation, no.

Q. And have you ever consulted with FDA in the preparation of an Establishment Inspection Report?

A. No.

Q. You said that you have consulted with -- I'm sorry, let me just ask a better question.

Have you ever consulted with medical device companies about regulatory topics?

A. Yes.

Q. Are you able to identify any of the companies for me?

A. On page 2 of my CV under "Professional Experience," you have "Interim CEO, Canopy Edge." That's specifically involved with preparing the product for regulatory submission.

Q. What is that product?

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Y. DAVID

A. It is a vascular catheter.

Q. Has a 510(k) -- I'm sorry. Will that be submitted as a 510(k) or a PMA, do you know?

A. It is still being reviewed.

Q. Any other medical device for which you've provided consulting on regulatory topics?

A. There are two other companies. One is called, I believe, Carmel Industries, C-A-R-M-E-L. And the other one is Begamed, B-E-G-A-M-E-D.

Q. What products?

A. Begamed.

Q. Were there specific products?

A. Begamed's product is laparoscopic suture, surgical instrument. And Carmel Industry is a software-based labor and delivery package.

Q. With respect to these three products that you've just identified, what is your role? What type of regulatory advice are you providing?

A. Wait a second. There is one more.

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There is one more and I can't remember the name. But their product, this additional entity, their product is a brain stimulator. And let me answer your question about what they asked me to do. The brain stimulator was going to submit a 510(k) and wanted to know what are the electrical safety terms and conditions that their testing needed to demonstrate compliance with.

Q. Okay.

A. IEC 60601-1.

The Carmel Industry, they wanted to know if there is a predicate device to their product that they can use for substantial equivalency.

The Begamed wanted to understand if their product will be qualified for 510(k) if there are substantial equivalent predicate devices and if there is a requirement for animal testing.

Q. Are sutures what class?

A. Class 2.

Q. What about the software-based labor and delivery package?

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A. I don't remember.

Q. Do you remember for the brain stimulator?

A. Class 2.

Q. And the vascular catheter is still under evaluation?

A. Correct.

Q. For the vascular catheter, what is the advice you're being asked about to provide?

A. What type of testing and information will be required for submission. Whenever we can take a break...

Q. Pardon? Sure.

THE VIDEOGRAPHER: We are going off the record at 15:20.

(Recess, 3:20 p.m. to 3:32 p.m.)

THE VIDEOGRAPHER: We are back on the record at 15:32.

BY MS. EATON:

Q. Dr. David, have you ever designed a patient warming device?

A. No.

Q. Have you ever made or published any

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presentation on Bair Hugger devices?

A. No.

Q. Before your work in this case, had you ever read any studies related to Bair Hugger devices?

A. No.

Q. At any time, have you performed testing related to Bair Hugger devices other than what we have discussed today?

A. No.

Q. At any time, have you performed research related to Bair Hugger devices that is not either reflected in your report or in what we have discussed today?

A. No.

Q. Have you undertaken any effort -- sorry, let me ask that differently.

Before your work in this case, had you reviewed any hospital practices with respect to Bair Hugger devices?

A. A specific brand name Bair Hugger, no. But relating to patient warming, yes.

Q. What had you reviewed related to patient warming prior to your work in this

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case?

A. Patient warming is a very important part of maintaining patient condition during disease management and following surgery or during trauma, so as part of my responsibility as director of biomedical engineering, for over 30 years I was involved in reviewing warming devices for adult and pediatric patients using either a literally oven-warmed blanket or devices that use fluids to warm patients or cool them or radiation-based devices that they are used in different environments.

The specific sensitivity that I became very familiar with the warming technology of patients is the one involving pediatrics, and we were having a very interesting project where we were trying to put warming devices in the emergency room, in the trauma center where the ambulances would bring babies, and determine how fast we can bring their body temperature up in those trauma situations.

And we were putting an infrared

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warming device in the ceiling of the trauma center and making testing and examination of mannequin, small size, having ice cube on them, and determine the temperature change of the body. And this specific example that I became intimately familiar with the issue of maintaining or warming patients under trauma situations.

The other example that I would like to bring in front of you is the neonatology arena where premature babies are born and are not able to maintain their body temperature, not because of trauma or disease, just because of their stage in early life. And those babies are tremendously sensitive to body core temperatures and it's very difficult to warm them up without causing skin damage.

So infant warmers, Isolettes, those are warm air, forced warm air contraption boxes that you put babies in and need to have specific monitoring for the humidity and the temperature inside to make sure that the babies are not drying up and not being basically cooked.

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And we did many studies and published several research papers on that, and I developed a protocol to -- how to test those devices later on in their life. So once we developed it, we learned how to use it and how to maintain and service it.

Q. Did you mean later on in the life of the device or --

A. Correct, yes. Thank you.

Q. That's what I thought in context as opposed to the life of the babies.

Did you do -- you meant the device?

A. Yes.

Q. Okay. Did any aspect of your testing or evaluation with respect to the Isolettes used for premature babies relate to contamination or infection risk?

A. It has that aspect and we have epidemiologists that were part of the study and that was their responsibility to collect the data and look at the statistics. So it was not something that I would do.

Q. Okay. Are you familiar with any of their determinations or the results of their

1 Y. DAVID  
2 surgical site infections?  
3 A. No, I do not.  
4 Q. Do you have any expertise in  
5 aseptic technique?  
6 A. Again, I have good working  
7 knowledge because this would be part of my  
8 involvement in equipment that is present  
9 during surgical procedures and in trauma rooms  
10 and I will be required to oblige by techniques  
11 such as that.  
12 Q. Is our earlier discussion today  
13 reflective of your involvement in those  
14 matters?  
15 A. It was a specific example. My  
16 involvement is much wider because I would be  
17 walking literally daily through the operating  
18 theater, visiting with the director of the  
19 operating room, visiting with surgeons, and  
20 looking at the various devices that are being  
21 used. So I have intimate interaction with  
22 that area.  
23 Q. Do you have responsibility -- I'm  
24 sorry, let me ask it differently.  
25 Have you had responsibility within

1 Y. DAVID  
2 hospitals for implementing infection control  
3 practices?  
4 A. I do not believe that I have the  
5 expertise in implementing infection control  
6 practices, but as it involves equipment in  
7 areas that might have risk of infections and  
8 contamination such as intensive care unit and  
9 moving ventilators and infusion pumps from one  
10 room to another, I have been involved with a  
11 team that would implement that type of  
12 practice.  
13 Q. Are you a medical doctor?  
14 A. No, I'm not a medical doctor.  
15 Q. Do you have any medical training?  
16 A. I do not have medical training.  
17 Q. Do you have expertise in heat  
18 transfer?  
19 A. Being a biomedical engineer, it was  
20 one of the courses that I took as part of my  
21 academic preparation. Heat transfer is an  
22 important physical phenomenon, and I studied  
23 and understand it. And I understand the  
24 principle operation.  
25 Q. You mentioned radiant heat earlier.

1 Y. DAVID  
2 Is that one form of heat transfer?  
3 A. Absolutely.  
4 Q. Is conductive heat another form of  
5 transfer?  
6 A. Correct.  
7 Q. And is convective heat another form  
8 of transfer?  
9 A. Like ovens, yes.  
10 Q. Have you ever participated in an  
11 infectious disease outbreak investigation?  
12 A. Yes.  
13 Q. How many times?  
14 A. Couple of times.  
15 Q. For which hospital?  
16 A. I'm not sure that I can discuss  
17 that. There might be some protective order  
18 there.  
19 Q. Okay. Was that in connection --  
20 well, was that in connection with litigation?  
21 A. No.  
22 Q. Both times you can remember, were  
23 they at the same hospital?  
24 A. Yes, I believe the same hospital.  
25 Q. Do you recall what the organism was

1 Y. DAVID  
2 ultimately that was at issue?  
3 A. No, I do not.  
4 Q. What was your role in the  
5 investigation?  
6 A. As the team investigate --  
7 investigated the possible source and  
8 contributing factors, my role was to ascertain  
9 the functionality of the medical devices in  
10 it.  
11 Q. Were any patient warming devices  
12 involved? Let me ask a different question.  
13 Did you investigate any patient  
14 warming devices?  
15 A. Yes, we did. We had the  
16 fluid-circulating devices at the time and they  
17 were part of the investigation.  
18 Q. What kind of fluid-circulating  
19 device?  
20 A. I can see the product in front of  
21 me. I don't remember the brand name.  
22 Q. Was it the -- I did not -- I'm  
23 sorry. I didn't -- do you recall the function  
24 of the device separate from the brand name?  
25 A. Yes. The device would heat fluids

Y. DAVID

additional materials that you have reviewed that are maybe not here today?

A. There's no additional material. We covered that subject totally. Ulatowski is one that is missing here. It will be added to the -- Dr. Ho, maybe it was after my report was written.

Q. I'm just wanting to make sure I understand all the materials you've reviewed. So if there's a place where you're -- could you take a look when you return to your home or office and just see if there perhaps are other materials that you have reviewed?

A. I certainly can do this, Counsel, and I will be happy to oblige. I can tell you that I made an effort to have all the material here today with us and I believe it is, except Tim Ulatowski.

Q. Okay. Sitting here today for purposes -- let me ask that differently.

For purposes of coming to your opinions in this case, did you rely on any understanding about what size bacteria cause surgical site infections?

Y. DAVID

A. For arriving at my opinion in this case, I fully appreciate the difference in sizes and the intensity of bioburdens of viruses, bacteria, fungi, as it relates to surgical site infection. I did not use that to arrive at my opinion. My opinions are biomedical engineering and risk assessment based.

Q. In assessing the risk that a difference in filtration at .2-micron size makes, what did you consult?

A. I consulted the literature, the medical and scientific literature, and I consulted the responses to answers by the defendant officers to a specific question about this subject.

Q. And are all the materials that you've just referenced identified in your report?

A. Absolutely.

Q. Okay. Did you conduct a literature search yourself?

A. The literature that I present in my report are a combination of my search and

Y. DAVID

counsel providing me with some.

Q. Are you able to tell me which items were provided by counsel?

A. Specifically which ones, no, I don't.

Q. And if you would open up, please, the binder that has literature in it just so that we could take a look at the specific index, whichever binder that is. I think it may be the one in your hand, I don't know. No? Sorry.

A. This is the one.

Q. Okay. Just see if by taking a look at that list you can identify any items that you believe were provided by counsel.

A. I would say that all those that has a numerical number at the end, 3MBH, a number that no question provided to me by counsel.

Q. Anything else?

(Document review by witness.)

A. I don't remember exactly, but some title like Forced Air Warming Blower Evaluation would be a title that I would come up and search and ask.

Y. DAVID

BY MS. EATON:

Q. Could I see the binder for one moment?

A. (Complies.)

Q. Thank you, sir.

What search terms did you use -- I'm sorry, let me ask that differently. What -- tell me about the search you conducted.

A. Well, I went on PubMed and visited the Texas Medical Center library and looked at mostly forced-air warming devices, and if there is something about filter efficacy. So this study is talking about evaluation, probably I picked it up in my search.

Q. Okay. Do you recall or did you record anywhere what search terms you used?

A. What search terms? No, I did not record that.

Q. Do you recall how many articles came back in response to your search terms?

A. Not really, no.

Q. Did you review the abstracts for all articles that came back in response to the

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search terms you used?

A. If it got late at night, I probably did not read all the abstracts but I made an effort to go through them and request those that I seemed to think applicable. I have -- I remember reading abstract from "Anesthesia," the journal, that looks like something I would like to have, but it ended up that the abstract was not really useful for me.

Q. What -- did you have any prespecified criteria for what an article needed to have before it would be one you would consider relevant?

A. No.

Q. What was your research question?

A. I'm not sure that I have research question.

Q. What was your -- what kind of article were you looking for?

A. I was looking for a comparative article, article that would have a good research design, hopefully similar environment, large population, and peer-reviewed.

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Q. Okay. What would it be comparing, what to what?

A. I wanted to see. I didn't have a pre-notion about what should be there.

Q. What were you looking to find out from these articles?

A. The level of knowledge within the professional community of the relationship between forced-air warming devices and surgical infection during orthopedic surgery; the possible methods that are used to identify that; the span of instrumental devices that are mentioned in those articles. That's about it.

Q. Okay. Are you familiar with the term "systematic literature review"?

A. Yes.

Q. That's not what you conducted.

A. Correct.

Q. Would you agree?

A. Correct.

(Sotto voce discussion.)

MS. EATON: What time is left on the record?

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THE REPORTER: We're at 6:17 right now.

MR. BANKSTON: Let's go off the record for just one second.

(Discussion off the stenographic record.)

THE VIDEOGRAPHER: We're going off the record at 17:36.

(Recess, 5:36 p.m. to 5:37 p.m.)

THE VIDEOGRAPHER: We're back on the record at 17- -- wait a minute.

We're back on the record at 17:37.

BY MS. EATON:

Q. When you reviewed the literature, did you locate any articles that evaluated whether the use of the Bair Hugger device increased the risk of infection and found that it did not?

A. Just to make sure that I understand your question, you're saying the article talked about increased infection but the conclusion or the finding was that it was not?

Q. Yes, that the test question was whether it would increase the risk of

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Y. DAVID

infection and it did not.

A. I don't think so.

Q. Did you locate any articles that concluded specifically that the Bair Hugger device decreased the risk of surgical site infection?

(Document review by witness.)

A. One of the articles that I indicate and consider is the review article of existing literature by Wood, Moss and Keenan, and I'm not sure, I need to read the study again, but maybe one of the articles there was saying there was no difference. I don't think that there was decrease, but no difference. I just need to read that paper again.

BY MS. EATON:

Q. If there were articles that established that the -- I'm sorry. If there were articles that reported that the use of a forced-air warming device during surgery decreased the risk of surgical site infection, would that be relevant to your consideration?

A. It would.

Q. If there were articles

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Q. Okay. Were you looking specifically for literature that related to the risk of joint infection following surgery?

A. No, I did not.

Q. Is it your testimony that orthopedic surgery carries a higher risk of infection than colorectal surgery?

A. It is my opinion that they are completely different conditions and present different challenges and cannot be compared.

Q. Do you know if the infection risk for orthopedic surgery is higher or lower than the infection risk for colorectal surgery?

MR. BANKSTON: Objection, form.

A. No, I don't have that knowledge.

BY MS. EATON:

Q. Do you have any knowledge about what the risk of infection is with any type of surgery?

A. I believe that I read recent statistics about that. Where was it... general statistics I read have the hospital-acquired infection, HAI, statistics relating to surgery. I don't remember as I

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sit here today specific numbers or quantities.

Q. Okay. Are you an expert in -- I'm sorry. Have you made any -- have you made any effort to study, in connection with your work for this case, what are the various risk factors that might impact infection risk in a patient during surgery?

A. When I read the articles, it was obvious that the beginning of the literature talk about the specific basic of infection routes and the sources. So every time I was reading the articles, it addressed that very clearly.

Q. In terms of all the things that might impact patient infection risk from a medical perspective, that's not something you're offering opinions about?

A. I am not.

Q. Have you seen a 500 series filter?

A. I don't know what you mean by "seen." I saw a drawing and I saw pictures in brochures.

Q. Okay. Do you recall what shape it is?

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A. It's different than the 750.

Q. Does it differ in size also from the 750?

A. It does.

Q. Have you done any comparison yourself of the filters?

A. There's no need for me to do it. Other expert did that.

Q. Who are you referring to?

A. The literature here in front of us has ample support material for that, so Hanfield is one, three -- letters, letters from defendant officers is another one that --

Q. I'm asking about anything you did, other than review materials.

MR. BANKSTON: Object to the form.

BY MS. EATON:

Q. Did you make a comparison of the two filters? Maybe --

A. There is --

Q. You only looked at a drawing of the 500 series filter. Is that correct?

A. Right.

Q. Okay. Do you recall what shape it

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was?

MR. BANKSTON: Object to the form.

A. Yeah.

BY MS. EATON:

Q. What shape was it?

A. Square.

Q. Do you recall the -- I'm sorry, what? Do you recall the size of it?

A. I didn't realize I'm in a memory test here. Shape, geometry, size, it's all in the material here. It's all described in detail. It is part of the binders that I have. If you want to take the time, I will go through the material and find it.

Q. I'd rather ask you a question about your report. If you --

MR. BANKSTON: Object to the preamble.

BY MS. EATON:

Q. Do you have any -- actually, what is the basis for your opinion that the Bair Hugger device is adulterated and misbranded? What specific features of it?

A. Very simply, the company misled the

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FDA by suggesting that they are a comparable product, that they changed characteristics of major components like the filter, did not communicate that, and yet marketed the device to consumer, confusing and misleading them.

Q. Do you have any basis for an opinion about industry standard other than compliance with FDA regulation?

A. In regard to what?

Q. In regard to the opinions you've expressed in your report.

MR. BANKSTON: I think we're done, Counsel.

MS. EATON: Could we just have an answer to this question?

MR. BANKSTON: Well, you're already past it but I was trying to give you some grace. But you started asking more questions after you've already passed the --

MS. EATON: I don't believe I've asked any question after I was past anything.

Could we have that question read

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back, please.

MR. BANKSTON: Can we get the time first?

THE REPORTER: It's 7:01:42-43 at this point.

(The reporter read back the following portion of the preceding record.)

"QUESTION: Do you have any basis for an opinion about industry standard other than compliance with FDA regulation?

"ANSWER: In regard to what?

"QUESTION: In regard to the opinions you've expressed in your report?"

(End of readback.)

A. I'll have to search that.

MR. BANKSTON: All right. I've got a few more questions.

FURTHER EXAMINATION

BY MR. BANKSTON:

Q. This -- do you mind if I see that? Do you remember being asked about this?

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A. Yes.

Q. And counsel wouldn't give it to you?

A. Correct.

Q. Because she said it wasn't in your report?

A. Right.

MS. EATON: Object to the form. I didn't say I wouldn't give it to him. I asked him if he recognized it.

MR. BANKSTON: And then you said he's not getting it because it's not in his report.

MS. EATON: He said, no, he didn't recognize it.

BY MR. BANKSTON:

Q. Counsel -- Dr. David, do you remember counsel telling you this wasn't in your report?

A. Yes.

Q. Okay. Can you go to page 48 for me. Can you read the fourth entry from the bottom for me?

A. "International consensus meeting on

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periprosthetic joint infection."

Q. Okay. So that is something you reviewed in this case?

MS. EATON: Objection to the form.

A. If it's listed here as document, yes.

BY MR. BANKSTON:

Q. The depositions that you reviewed in this case, did they have exhibits to them?

A. Yes.

Q. Do you remember in any of the depositions in this case or in more than one or none of them, was ECRI ever discussed in those depositions?

A. Yes.

Q. Now, in your report, you did not specifically list each and every exhibit of every deposition I see. That's correct?

A. Correct.

MS. EATON: Object to the form.

BY MR. BANKSTON:

Q. Okay. When reading the depositions that had exhibits, those exhibits that are discussed in the deposition, those are parts

# **EXHIBIT DX61**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS

## **Bair Hugger Warmer Does Not Increase Microbial Contamination in the Operating Room.**

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DALLAS, TEXAS. 75235-9068

### **ABSTRACT**

To determine if the Bair Hugger warming device increases contamination in the operating room we conducted microbial surveillance in twenty cases randomly assigned to receive patient warming with (BH) or without Bair Hugger (NBH). Microbial culture plates were exposed in the O.R. during cases and rates of contamination were determined by a microbiologist blinded to the group. There were no detectable differences in contamination rates between groups, (NBH mean = 7.33 colonies, sd = 1.64; BH mean = 7.27 sd = 1.55) and no post-operative wound infections. The Bair Hugger does not increase microbial contamination in the operating room.

### **INTRODUCTION**

Maintenance of patient temperature during anesthesia and surgery is an important task for the anesthesiologist. The BAIR HUGGER forced-air warming system (Augustine Medical Inc., Eden Prairie, MN) consists of a filtering and heating unit with a flexible hose to inflate a disposable patient cover made of paper and plastic. Filtered and warmed air is directed over the patient via numerous small holes in the cover. Currently no data exists regarding the potential of the device to cause microbial contamination in the operating room or peri-operative infection in surgical patients. This study was designed to determine if the Bair Hugger system increases operating room contamination.

### **MATERIALS AND METHODS**

Twenty adult ASA class I and II patients scheduled for oral or maxillofacial surgery were randomly assigned to two groups, Bair Hugger (BH) or non Bair Hugger (NBH), as the warming method for each case. We surveyed the same operating room, surgical, anesthesia and nursing staff. Normal access and activity in the O.R. was permitted during the study. Sets of plates comprising

two microbial culture media, Chocolate Agar (CAP) for bacteria and Sabaraud Agar (SAB) for fungi were placed at each of six specific locations around the operating room (diagram 1). An initial case was studied without use of the Bair Hugger to determine the relationship between contamination of the plates (expressed as number of colonies per plate) and duration of exposure. Six sets of two plates were placed in each of the six locations just before the start of surgery and sets of two were removed from each location every twenty minutes.

In later cases one set of plates was exposed in each location for the duration of the case or a maximum of two hours. After incubation the number of colonies per plate were counted and identified by genus by one qualified microbiologist who was blinded to location, warming method and duration of exposure. Data were evaluated using analysis of covariance and repeated measures of covariance treating the six locations as six levels of the repeated factor. The covariate was always duration.

## RESULTS

In the first case bacterial colony count and duration of exposure were linearly related; the rate of contamination was constant (figure 1). In the other cases with exposure times ranging from 30 to 120 minutes we were unable to identify any differences in contamination rates between groups (table 1). Some locations showed consistently higher levels of contamination than others however the differences were not influenced by the use of the Bair Hugger. All patients were reviewed at routine follow-up. No patient in either group developed a post operative wound infection.

## DISCUSSION

The Bair Hugger maintains a temperature controlled micro-environment for the patient. In addition to minimizing radiant and convective heat loss it also provides patient warming. Potential benefits include faster recovery from anesthesia; lower incidence of complications such as shivering, problems with blood pressure, increased oxygen requirement and disordered blood coagulation; and increased comfort (1,2). The device may cause alteration of air movements within the O.R. and it is unknown if this results in increased contamination of the surgical field or operating instruments. Our microbial surveillance of twenty cases was intended to detect gross changes in contamination.

The Bair Hugger did not increase contamination of the operating room in our study. This may be due to several factors. All air passing through the Bair Hugger heating unit passes through a 0.2 $\mu$ m filter on the inlet. Also, the patient cover can be sealed at one end by adhesive strip to prevent flow of air directly into the surgical field. Further, output of warmed air is 35L/min or 2100L/hr, representing only a small fraction of the normal operating room ventilation of about 10 room changes per hour, or about 750,000L/hr. Finally, the velocity of the moving air and thus its potential for causing turbulence is low as the 35L/min is directed over the patient via small holes in the patient cover.

The benefit of the O.R. model Bair Hugger is maintenance of patient temperature intra-operatively. The risks of this method of thermal maintenance are not completely known but this study of bacterial contamination in six locations in the operating room reveals that the Bair Hugger does not increase the rate of contamination. We conclude that its use does not increase the risk of surgical wound infection.

#### REFERENCES

1. Seminars in Anesthesia 1983, vol II; 3, 183-196.
2. Seminars in Anesthesia 1983, vol VII; 1, 3-10.

# DIAGRAM 1

## Plan of O.R.

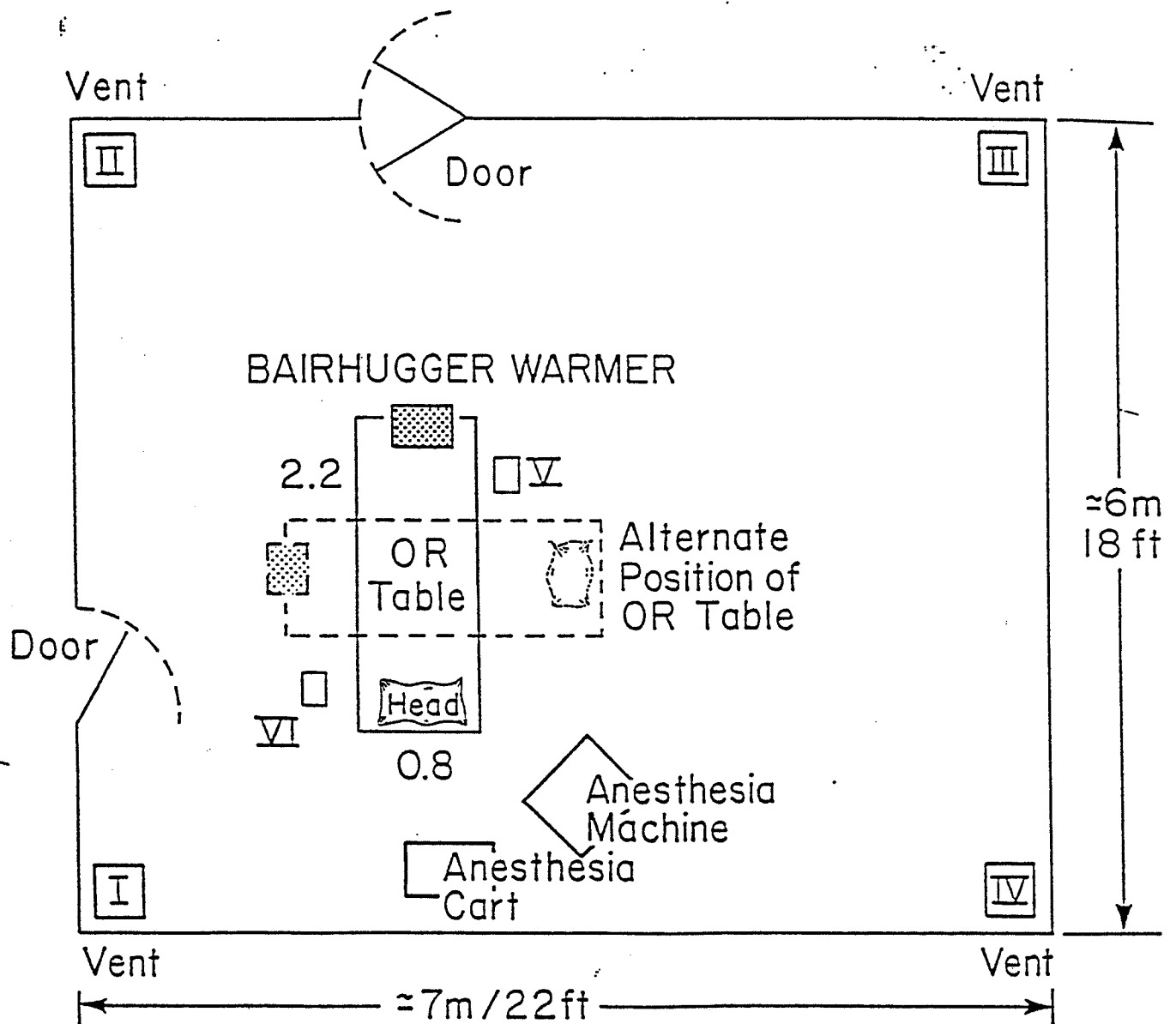
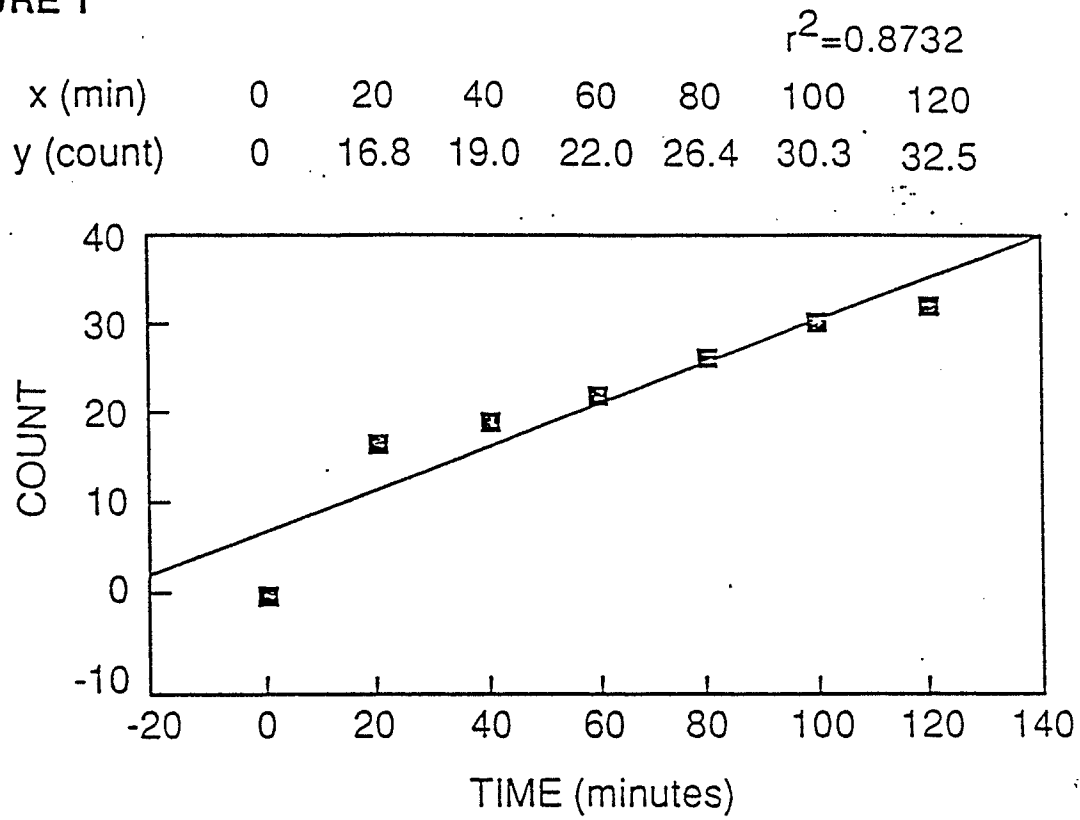


FIGURE 1



**TABLE 1**

Location	NBH mean	SD	BH mean	SD	P value
I	3.19	1.0	3.37	0.91	0.9345
II	2.37	0.67	2.65	0.71	0.5296
III	3.00	0.72	3.03	0.79	0.9299
IV	1.97	0.75	2.62	0.75	0.1068
V	3.88	1.60	2.95	1.10	0.0501
VI	3.06	1.05	3.21	0.86	0.7278
ALL	<u>7.33</u>	<u>1.64</u>	<u>7.27</u>	<u>1.56</u>	<u>0.7067</u>
Corner	5.30	1.21	5.79	1.38	0.5878
Table	5.01	1.55	4.39	1.03	0.2138
Door	4.36	1.06	4.51	1.07	0.9984
Vent	3.04	0.87	3.69	0.94	0.1976
Time	81	41	96.5	36.5	

# **EXHIBIT DX62**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS

# ANESTHESIA &

# ANALGESIA

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## Editorials

Effect Site Equilibration Time  
Ulnar Nerve Palsy — Is It Preventable?

## Original Articles

Factors Influencing Thiopental Dose  
Intravenous Anesthetics and Myocardial Potassium Currents  
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Cardiac Metabolic Effects of Halothane  
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Novel Demonstration of the Second Gas Effect  
Effect of PEEP on Phrenic Motoneuronal Activity  
Onset of Neuromuscular Blockade — Variables  
Effect of Pancuronium and Vecuronium on Each Other  
Resident Work Hours

## Cardiovascular Anesthesia

Human Erythropoietin, Autologous Blood, and CABG  
Dopamine Uptake and Cardiopulmonary Bypass

Hemodilution, the Stress Response and Outcome

## Regional Anesthesia and Pain Management

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# ANESTHESIA & ANALGESIA

*Journal of the International Anesthesia Research Society*

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# Convective Warming Therapy Does Not Increase the Risk of Wound Contamination in the Operating Room

Robert S. Zink, MD, and Paul A. Iaizzo, PhD

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Although convective warming therapy is effective in preventing hypothermia in anesthetized patients, little is known concerning the potential risks of its use. Hence, this balanced cross-over study was designed to determine if the use of convective warming therapy increased the risk of wound contamination. For 4 h, eight healthy male volunteers (aged 20–25 yr) lay supine on an operating room table with their lower bodies and legs covered with a warming cover and sterile surgical drape. The convective warming therapy was administered for 2 h. The other 2 h served as the

control. In each session, culture plates were placed directly on the subject's abdomen through an opening in the drape. Tympanic membrane and leg skin temperatures were significantly higher with active warming. No significant differences in the number of bacterial colonies were observed between the two study periods. It was concluded that convective warming therapy, when appropriately applied, does not increase the risk for airborne bacterial wound contamination in the operating room.

(Anesth Analg 1993;76:50–3)

Wound infection is an important postsurgical problem. A wound infection complicates the recovery from an operation, can prolong the hospital stay, and substantially increases the cost of care. It has been estimated that a postoperative wound infection can increase the patient's stay approximately 6–14 days (1,2). In one study, decreasing the postoperative infection rate from 4.2% to 1.6% saved that institution approximately \$750,000 over a 5-yr period (3). Reported rates for wound infection can range from 1% to 5% for "clean" cases and up to 6% for all cases (4,5).

Following studies in which the settling of bacteria onto sedimentation plates in the operating room were observed, specific guidelines for the rate of air turnover in the operating room were made by the Centers for Disease Control (5). A turnover rate of 20 exchanges per hour is considered necessary to minimize this potential source of contamination (6). With the recent advent of using convective based warming and/or cooling devices with airflows up to 15 m<sup>3</sup>/min in close proximity to surgical patients, the potential risk for airborne bacterial contamination warranted reassessment. The present study was undertaken to test the hypothesis that the use of such therapy would

be unlikely to increase a patient's risk for wound contamination during surgery.

## Methods

This study was approved by the University of Minnesota Human Subjects Committee and was performed in three different operating rooms at the University of Minnesota Hospital during a 3-wk period. Eight healthy male volunteers (aged 20–25 yr), free of any cutaneous or systemic disease, and not having taken any antibiotics within a month before the study, gave informed consent for participation. Each subject was instructed to lay supine and relatively motionless on an operating room table for two consecutive 2-h trials. Their lower body and legs were covered with an operating room convection warming cover (Augustine Medical Inc., Eden Prairie, MN) with the adhesive edge securely applied at the level of the umbilicus. A sterile surgical drape with a chest opening was placed over the subject from the feet to the neck. The subject's skin was not surgically prepared or disinfected in any way. All subjects wore briefs and a surgical mask throughout the study.

The subjects inserted their own tympanic temperature probe (Mon-a-Therm Inc., St. Louis, MO) into their right ears. The wires were then secured to the patients by adhesive tape to prevent accidental removal. Self-adhesive skin temperature probes (Mon-a-Therm Inc.) were applied to the mid-thigh and the abdomen below the sternum. Temperatures were re-

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**Table 1.** Airborne Bacteria Detected During 2-h Trial Periods With and Without the Use of Convective Warming Therapy: Five Different Bacterial Types Were Cultured

Subject and culture type†		Control (no therapy)	Convective warming therapy
1	SBA	$\alpha$ -Streptococcus: 2 colonies Coagulase (-)-Staph: 1 colony	*Sterile
	Mac CNA	Sterile Coagulase (-)-Staph: 1 colony	Sterile Coagulase (-)-Staph: 1 colony
2	SBA	*Coagulase (-)-Staph: 2 colonies Bacillus: 1 colony	Coagulase (-)-Staph: 3 colonies
	Mac CNA	Sterile Coagulase (-)-Staph: 1 colony	Sterile Sterile
3	SBA	Coagulase (-)-Staph: 3 colonies	*Coagulase (-)-Staph: 4 colonies Micrococcus: 1 colony
	Mac CNA	Sterile Coagulase (-)-Staph: 2 colonies	Sterile Sterile
4	SBA	Coagulase (-)-Staph: 2 colonies Corynebacteria: 2 colonies	*Coagulase (-)-Staph: 2 colonies Micrococcus: 1 colony
	Mac CNA	Sterile Coagulase (-)-Staph: 2 colonies Corynebacteria: 1 colony	Sterile Coagulase (-)-Staph: 1 colony
5	SBA	*Coagulase (-)-Staph: 15 colonies Corynebacteria: 1 colony	Coagulase (-)-Staph: 2 colonies
	Mac CNA	Sterile Coagulase (-)-Staph: 15 colonies Corynebacteria: 1 colony	Sterile Sterile
6	SBA	*Coagulase (-)-Staph: 2 colonies	Coagulase (-)-Staph: 1 colony Corynebacteria: 1 colony
	Mac CNA	Sterile Sterile	Sterile Coagulase (-)-Staph: 1 colony
7	SBA	Coagulase (-)-Staph: 2 colonies	*Corynebacteria: 1 colony
	Mac CNA	Sterile Sterile	Sterile Coagulase (-)-Staph: 1 colony
8	SBA	*Coagulase (-)-Staph: 1 colony	Sterile
	MAC CNA	Sterile Sterile	Sterile Sterile

SBA = sheep blood agar; Mac = MacConkey; CNA = colistin-nalidixic acid; Staph = staphylococcus.

\* = first set of data for that individual.

corded at 15-min intervals, and arterial blood pressures and heart rates were recorded using a Colin BP8800 automated blood pressure monitor (Colin Electronics Co. Ltd.) at 30-min intervals throughout the study. Three different types of bacterial culture plates were fastened to each subject's abdomen with double-sided tape at the start of each trial period, generating six plates per subject. The plate types were: 1) sheep blood agar (a nonspecific medium; six or more bacteria types may be detected); 2) MacConkey agar (a primary isolation medium for recovery of aerobic and anaerobic Gram-negative bacteria); and 3) Colistin-Nalidixic Acid agar (inhibitory to Gram-positive organisms; six or more bacteria types may be detected). Subjects were randomly divided into two groups. One had the convective cover in place, but not inflated for the first 2-h period. The blowers (Bair Hugger Model 500, Augustine Medical, Inc.) were operational on the

medium setting for the latter 2-h period. The other group had their trial periods reversed: i.e., the blowers were on initially. In this design, each subject served as his own control. A blower setting of medium corresponds to an airflow of 10.7 m<sup>3</sup>/min at a temperature of 38 ± 3°C. At the end of the study period, the plates were cultured at 35°C for 48 h and read for the presence and type of bacteria.

Statistical significance of the temperature, heart rate, and blood pressure data was determined using Student's *t*-test, whereas the bacterial culture data were analyzed by a two-way analysis of variance. A *P* value < 0.05 was considered significant.

## Results

No significant difference in the total number of bacterial colonies isolated on culture plates was observed

**Table 2.** Arterial Blood Pressure, Heart Rate, and Temperature Data at Selected Time Points for the Subjects in Each Study Group

Control-therapy subjects 2, 5, 6, 8	Time zero	1 h of control	End of control	1 h of warming	End of warming
Mean BP (mm Hg)	98 ± 6.2	96 ± 3.3	95 ± 6.4	93 ± 3.1	98 ± 2.6
HR (beats/min)	72 ± 8.6	66 ± 7.5	66 ± 8.3	63 ± 6.7	70 ± 11.3
Tympanic temp (°C)	37.3 ± 0.4	36.7 ± 0.2	36.7 ± 0.3	36.8 ± 0.3	36.8 ± 0.2
Thigh temp (°C)	33.5 ± 1.0	35.2 ± 1.4	35.1 ± 1.4	37.1 ± 0.6	37.1 ± 0.4
Abdominal temp (°C)	33.7 ± 1.4	33.2 ± 1.2	32.2 ± 1.7	32.1 ± 1.9	32.9 ± 1.1
Therapy-control subjects 1, 3, 4, 7	Time zero	1 h of warming	End of warming	1 h of control	End of control
Mean BP (mm Hg)	99 ± 5.0	94 ± 7.3	93 ± 7.8	95 ± 7.5	94 ± 7.7
HR (beats/min)	77 ± 7.0	70 ± 7.1	69 ± 10.4	64 ± 5.1	71 ± 1.5
Tympanic temp (°C)	36.9 ± 0.2	36.8 ± 0.2	36.7 ± 0.2	36.5 ± 0.3	36.5 ± 0.3
Thigh temp (°C)	34.5 ± 1.3	33.0 ± 1.3	37.0 ± 0.2	32.1 ± 0.6	35.3 ± 0.3
Abdominal temp (°C)	34.0 ± 0.7	36.9 ± 0.2	33.1 ± 0.8	35.2 ± 0.3	32.1 ± 0.8

BP = blood pressure; HR = heart rate; temp = temperature.

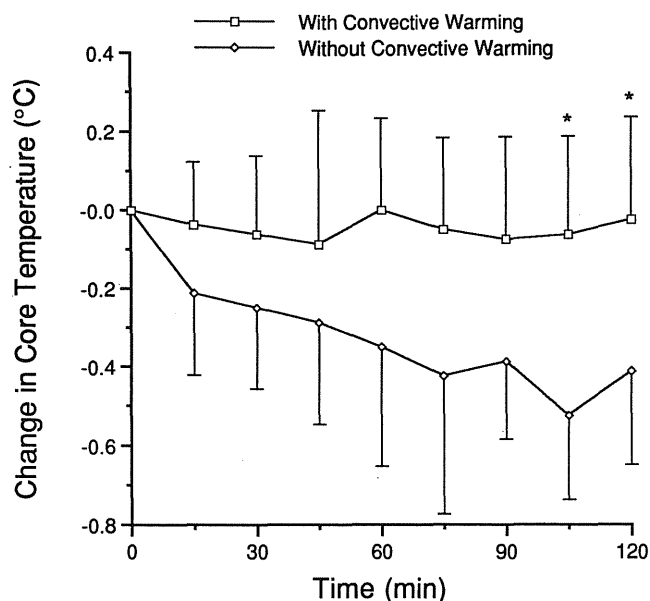
between the two study periods. Five types of bacteria were isolated from the control plates: coagulase (–)-staphylococcus, corynebacteria, micrococcus,  $\alpha$ -streptococcus, and bacillus. Only the first three types were isolated from the study plates (Table 1). The number of colonies of coagulase (–)-staphylococcus was significantly different between the groups, the control group having more colonies than the study group ( $P < 0.05$ ).

There was no difference in arterial blood pressure or heart rate between the two trial periods (with and without active warming) or between the two groups

(i.e., warming either initially or following a control period). In each group, there was a tendency for the heart rate to increase toward the end of each period, possibly in anticipation of completion (Table 2). Similarly, the temperature of the exposed skin of the abdomen in the region of culture dish placement was not significantly different between groups (Table 2). The averaged tympanic membrane temperatures for the subjects in the control therapy group decreased initially then rose slightly during warming, whereas temperatures of the other subjects decreased slightly during both warming and control (Table 2). Pooled tympanic membrane temperature data from both groups are presented in Figure 1. As expected, thigh skin temperatures were significantly higher during warming ( $P < 0.05$ ). No subject reported feeling uncomfortably cold or began to shiver during either part of the study.

## Discussion

With the potential for convective-based warming devices to become commonplace in the operating room, it is important to assess their potential contribution to airborne bacterial contamination. The use of these devices raises some concern because they can contribute high air flows in close proximity to the patient. The relation between air movement and aerosolization of bacteria has been studied for years. The most significant sources of airborne bacteria are the patient (7), the surgical team (8), and even personnel in the corridors surrounding the operating room suite (6). Methods studied to combat this threat include "ultra-clean" laminar air flow rooms (8) and clothing with small pore size to limit the shedding of bacteria-laden skin particles (9).



**Figure 1.** The effects of convective warming on core temperature (tympanic). The temperature data were normalized (per individual), and data for all subjects were pooled. With active warming, the core temperature was stable, whereas without warming a significant decrease was noted by the end of the control periods. \* Significant difference ( $P < 0.05$ ).

This study was designed to evaluate the settling of bacteria at a simulated surgical site, an obvious prerequisite for the development of a wound infection via airborne bacteria. This design could be considered as simulating a "worst case scenario" because the subject's skin was not disinfected in any way. In addition, the awake subjects were free to move their upper extremities and talk, thus possibly contributing to the number of airborne particles. We hypothesize that if the subjects would have received a full antibacterial treatment prior to the study, the number of colonies cultured on the plates might have been fewer. Although there were no surgical personnel in the operating room suite, the investigators (who were not scrubbed) were frequently moving in and out of the room.

The bacteria most commonly detected in the present study was coagulase (-)-staphylococcus, an organism commonly associated with aerosolized contamination and a leading cause of postoperative wound infections (7). Of surprise was the absence of *Staphylococcus aureus*, which is among the most common pathogens isolated in studies of serious wound contamination and infection (8). A possible explanation for this difference between studies could be in the product design: the floor mounted blower used in the present study is designed with a 0.2- $\mu$ m filter at the air intake, this size being much smaller than the average size of bacteria-carrying particles (20  $\mu$ m) (9). In addition, the adhesive strip on the warming cover is applied at the waist, serving to direct the flow of air away from the surgical site and the surgical personnel.

As predicted, the decrease in core temperature observed in these unanesthetized subjects was much less than that commonly seen in anesthetized patients placed in a similar operating room environment (i.e., 1°C) (10,11). Anesthetized patients are considered to have disruption within their thermoregulatory mechanisms as well as anesthetic-induced cutaneous vasodilatation (12).

In conclusion, convective warming therapy, when properly applied to direct the flow of air away from the surgical site, does not increase the risk for wound contamination in the operating room.

We thank Dr. Richard J. Palahniuk for his comments; Dr. Frank Martin for his statistical consultation; and the Department of Microbiology for their assistance with the bacterial cultures.

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# **EXHIBIT DX63**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS

## ABSTRACTS

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TITLE: CONVECTION WARMING IN THE OPERATING ROOM: EVALUATION OF BACTERIAL SPREAD WITH THREE FILTRATION LEVELS

AUTHORS: W. E. Dirkes, Jr., M.D.  
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With the recent increase in use of convective heating for warming patients in the operating room, there has been concern regarding possible increases in surgical infections. Several manufacturers have produced convective warming machines with varying degrees of filtration. One previous paper studied a 0.2 micron filter and 95% efficient machine and blanket and found no increase in bacterial spread (1). Our study was designed to test three different units with three levels of filtration and to test the filtration alone.

The units tested were a WarmAir Model 130 with 5 micron filtration, a BairHugger 550 with 0.2 micron filter and 95% efficiency rating, and a WarmAir Model 133 with a 0.02 micron filter with 99% efficiency. The machines were placed in a standard, fully equipped operating room at the head of the OR table. A plate of cultured beta hemolytic strep was placed 10 inches from the filter inlet. A fresh agar plate was then placed 12 inches from the outlet of the convective unit. The machine was then turned on. Group 1: WarmAir Model 130 - high temperature. Group 2: WarmAir Model 130 - ambient temperature. Group 3: BairHugger - ambient temperature. Group 4: WarmAir Model 133 - ambient temperature. The machines were kept on for two hours for each sampling time. A total of ten samples for each group were obtained.

Group 1 had one plate that grew one colony of a probable staphylococcus species. Group 2 had one plate that had six colonies of coagulase negative staphylococcus and one plate that had two colonies of coagulase negative staphylococcus. Groups 3 and 4 were all no growth. There was no transmission of beta hemolytic streptococcus by the convective warming units in any of the groups.

The convective warming units, as tested, are effective in preventing the transmission of large loads of bacteria through the filtration system. In no case with these machines was a marker bacteria of beta hemolytic streptococcus transmitted through the system. This includes a machine with only a 5 micron filter. Although the filtration systems tested all appeared to be effective, this study did not look at further contamination which may be possible due to the increased movement of air over unsterile fields. However, this study does show that convective warming with a filter rated up to 5 microns in size is effective in preventing the transmission of bacteria through the system.

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## APPARATUS

## Convection warmers – not just hot air

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## Summary

We sought to determine whether the forced air convection warmers (nine Bair Huggers, Augustine Medical, and one Warm Touch, Mallinkrodt Medical) used in our operating theatres could be a source of microbial pathogens. Agar plates were placed directly in the air stream of the warmers. Four of these grew potentially pathogenic organisms. When the warmers were set to blow through perforated blankets, no growth occurred. Three of the warmers were swabbed and sites of colonisation were found in their hoses. After fixing a microbial filter to the end of the hose, organisms were no longer detectable. We conclude that these warming devices are a potential source of nosocomial infection. They should only be used in conjunction with perforated blankets, should have their microbial filters changed regularly and their hoses sterilised. The inclusion of a microbial filter into the nozzle of the hose could be incorporated into the design of the warmer.

**Keywords** *Equipment; temperature blankets. Infection. Hypothermia.*

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Accepted: 3 May 1997

Forced air convection warming devices have revolutionised our management of hypothermia, especially in the operating theatre. They have proved to be very efficient in providing thermal homeostasis during surgery [1, 2]. The maintenance of normothermia has been associated with a reduction in the incidence of postoperative surgical wound infection [3]. Peri-operative hypothermia is also associated with several other complications, including shivering, decreased drug metabolism and clearance, and impaired wound healing [4]. Thus far, studies suggest that convection warming does not increase microbial contamination in the operating room [5, 6].

Convection warmers entrain environmental air through a microbial filter (0.2 µm pore size). The air is heated and blown through a detachable hose. The manufacturers of convection warmers recommend that these devices be used only in conjunction with a specialised blanket with perforations on its underside. They suggest that the filter be changed every 6 months or after 600 h of usage.

In practice, these devices are frequently used without specialised blankets with warm air blowing directly onto

the patient. Filters are often not replaced, according to the manufacturer's recommendations (Augustine Medical).

We set out to determine whether these devices blow contaminated air. Thereafter, we sought to ascertain whether the use of perforated blankets could prevent the detection of such contamination. We further tried to locate possible sites of contamination. Finally, we sought to establish whether placing a microbial filter on the end of the hose of the warming devices might filter out organisms.

## Methods

A vascular operating theatre, which is cleaned daily with Bacterex-C® (disinfectant cleaner containing organic chloride and detergent compounds), was chosen as the site of the experiments. Operating theatre temperature ranged between 21 and 23 °C and humidity between 61 and 67%. The investigators wore full operating theatre clothes and sterile gloves and remained at a distance of at least 1 m from the equipment for the duration of the experiments. Agar plates were on sterile towels on the operating table.

**Experiment 1: are microbes present in the air stream of warmers?**

Ten intra-operative patient warming devices (nine Bair Huggers, Augustine Medical, and one Warm Touch, Mallinckrodt Medical) were assessed. Each warmer was placed sequentially on a standard place on the floor. The nozzle of the hose was suspended from an infusion stand 40 cm above two agar plates. The machine was turned on to blow air at 43 °C over the plates for 5 min. There was a break of 5 min between each machine. Control plates were placed at the beginning and end of the experiment with no warmer blowing.

**Experiment 2: do perforated blankets reduce microbial contamination?**

Two of the warmers which had yielded early growth on agar plates were assessed further. The warmers were attached to infusion stands. Perforated blankets were elevated over agar plates. The warmers were set to blow air at 43 °C through the blankets over the plates for 30 min. Control plates were placed under a blanket for 30 min without air blowing. Warmed air was also blown directly onto agar plates as had been done in Experiment 1.

**Experiment 3: can colonisation be localised?**

Three of the warmers whose agar plates had grown organisms were swabbed from both sides of the internal microbial filter and from the inside of the hose at its proximal (warmer) and distal (patient) ends.

**Experiment 4: can contamination of the air stream be reduced?**

The same three warmers were set to blow onto agar plates for 5 min with and without microbial filters fitted to the distal ends (nozzles) of their hoses. The filters used were

DAR Hygrobac Filters for breathing systems (DAR S.p.A). These serve as both bacterial and viral filters.

**Microbiology methods**

Two agar plates were used to sample warmed air from each machine. One contained dextrose agar with chloromycetin (DAC) and the other 5% horse blood agar. Following completion of each experiment, each plate was wrapped in laboratory film. Swabs and plates were transported to the laboratory immediately, where swabs were plated onto DAC and 5% horse blood agar. The plates were incubated at 37 °C and inspected every 2 days for growth. Blood plates were kept for a total of 7 days and DAC plates for 1 month before being called negative. Visible colonies growing on the plates were picked off and identified according to standard bacteriological and fungal laboratory procedures.

**Results****Experiment 1: microbes are present in the air streams of warmers (Table 1)**

There was a pure growth of *Aspergillus fumigatus* on both control plates. Organisms grew on plates from four of the 10 (40%) warmers. The organisms cultured were *Staphylococcus xylosus* (from two plates), *S. epidermidis* (from one plate), *Corynebacterium* spp. (from one plate) and *Cryptococcus albidus* (from one plate). *A. fumigatus* was also isolated from two of the test plates.

**Experiment 2: perforated blankets reduce microbial contamination (Table 2)**

The control plates grew no organisms. The agar plates directly in the stream of the warmers both grew

Machine type	Number	Hours in use	Usual theatre	Organisms cultured
Bair Hugger 500E	1		general surgery	none
Bair Hugger 500E	2		neurosurgery	none
Bair Hugger 505	3	245.6	cardiac surgery	<i>Corynebacterium</i> spp.
Bair Hugger 505	4	426.2	paediatric surgery	none
Bair Hugger 505	5	111.1	paediatric surgery	<i>Staphylococcus xylosus</i> , <i>Aspergillus fumigatus</i>
Bair Hugger 505	6	157.7	recovery room	none
Bair Hugger 505	7	112.9	paediatric surgery	none
Bair Hugger 505	8	666.2	general surgery	<i>Cryptococcus albidus</i> , <i>A. fumigatus</i> , <i>S. xylosus</i>
Bair Hugger 505	9	718.5	general surgery	none
Warm Touch 500	10		cardiac surgery	<i>S. epidermidis</i>
Control 1				<i>A. fumigatus</i>
Control 2				<i>A. fumigatus</i>

**Table 1** Microbes present in the air streams of warmers.

**Table 2** Microbial contamination with and without the use of perforated blankets.

Machine number	Method used	Organisms cultured
5	Under blanket for 30 min	none
5	In direct air stream for 5 min	<i>S. epidermidis</i> and <i>Corynebacterium</i> spp.
8	Under blanket for 30 min	none
8	In direct air stream for 5 min	<i>S. epidermidis</i>
Control	Under blanket for 30 min without warm air blowing through	none

**Table 3** Sites of colonisation in three warmers.

Machine number	Site of swab	Organisms cultured
3	inside of filter	none
3	outside of filter	<i>Staphylococcus aureus</i>
3	proximal hose	<i>Corynebacterium</i> spp.
3	distal hose	<i>S. epidermidis</i> , <i>Corynebacterium</i> spp.
5	inside of filter	none
5	outside of filter	<i>S. epidermidis</i> , <i>Aspergillus niger</i> , <i>A. fumigatus</i>
5	proximal hose	<i>Bacillus</i> spp.
5	distal hose	none
8	inside of filter	none
8	outside of filter	<i>S. epidermidis</i> , <i>Bacillus</i> spp., <i>A. niger</i>
8	proximal hose	<i>Corynebacterium</i> spp., <i>A. fumigatus</i>
8	distal hose	<i>A. fumigatus</i>

organisms (*S. epidermidis* in two and one additionally grew a *Corynebacterium* spp.). Those which had warm air blown on them through the perforated blankets grew no organisms.

#### Experiment 3: microbial colonization of warmers is detected (Table 3)

Swabs from the outer surfaces of the filters from three warmers grew *Staphylococcus aureus*, *S. epidermidis*, *A. fumigatus*, *Aspergillus niger* and *Bacillus* spp. None of the swabs from the inner surfaces grew organisms. The proximal hose swabs grew *Corynebacterium* spp., *Bacillus* spp. and *A. fumigatus*. The distal hose swabs grew *S. epidermidis*, *Corynebacterium* spp. and *A. fumigatus*.

**Table 4** Contamination with and without a microbial filter attached to the nozzle of the hose of the warmer.

Machine number	Method used	Organisms cultured
3	blowing through filter	none
3	direct blowing	<i>Acinetobacter lwoffii</i>
5	blowing through filter	none
5	direct blowing	<i>Staphylococcus epidermidis</i>
8	blowing through filter	none
8	direct blowing	<i>S. epidermidis</i>

#### Experiment 4: a microbial filter attached to the nozzle of the hose reduces contamination (Table 4)

Plates placed directly in the air streams of the three warmers grew *Acinetobacter lwoffii* and *S. epidermidis*. When microbial filters were fitted to the nozzles of the same warmers, there was no growth.

#### Discussion

Infection control is of paramount importance to all practitioners, particularly at a time when multidrug resistant organisms are emerging. We have detected a potential source of nosocomial infection at our hospital. The filters in convection warmers (when replaced regularly) should protect against entrained bacterial and fungal pathogens, but may not prevent colonisation in the machines distal to the filters.

Our results indicate that, when air was sampled directly from the warming devices (without the use of the recommended perforated blankets), microbial pathogens were detectable in almost half of the devices tested. When the experiment was repeated with the use of the recommended blankets, contamination of sampled air (through the blankets) was no longer detected.

Organisms cultured in the experiments are typical of skin flora (*S. epidermidis*, *S. xylosus*, *A. lwoffii* and *Corynebacterium* spp.) or are ubiquitous organisms present in the

environment (*A. fumigatus*, *A. niger*, *Bacillus* spp. and *C. albidus*). These organisms are potentially pathogenic, especially in immunocompromised patients and when prosthetic devices are present (e.g. indwelling central lines, heart valves).

Following this study, we have altered policy in our hospital. We now ensure that forced air convection warmers are only used when attached to perforated blankets. We also recommend that microbial filters be changed as specified by the manufacturer and that detachable hoses are sterilised regularly. A microbial filter fitted to the nozzle of the hose could be incorporated into the design of the warmer to reduce the risk of contamination.

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# **EXHIBIT DX65**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS



# Convection warmers—a possible source of contamination in laminar airflow operating theatres?

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**Summary:** This work results from concerns that forced-air convection heaters applied to patients in the operating theatre might interfere with ultra-clean ventilation system and thus be a potential source of wound contamination. Air samples were taken in the operative field and the bacterial load calculated by estimating the number of colony forming units per cubic metre of air (cfu/m<sup>3</sup>). Six tests were carried out, two in empty theatres and four during standard orthopaedic operating lists. Differences were seen between empty theatres and those standing empty for short periods during busy operating lists. Increases were seen on entry to theatre of staff and patients with the convection heaters off. A further small rise was seen after the convection heaters were turned on when applied to patients. This study showed that use of warm air convection heaters on patients produced a small increase in the number of colony forming units in ultra-clean air theatres but the levels were unlikely to have clinical significance. By far the greatest effect on numbers was movement and presence of the patient and theatre staff in the theatre.

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**Keywords:** Convection heaters; operating theatre; ultra-clean air; infection.

## Introduction

Laminar airflow or ultra-clean ventilation systems were introduced in the 1960s and are now a common feature of operating theatres. Their function is to decrease the bacterial load in the theatre,<sup>1,2</sup> with the aim of reducing the incidence of surgical wound infection.<sup>3</sup> Forced-air convection warmers, used regularly in operating theatres, have revolutionized the management of patient hypothermia during operation, with a secondary reduction in the incidence of postoperative wound infection.<sup>4</sup> These

devices (which are often located on the floor) are used in conjunction with a specialized blanket with perforations on the underside applied to the patient. Theatre air is passed through a microbial filter, heated, and blown through a detachable hose. We set out to determine whether forced-air convection warmers might interfere with the principle of ultra-clean ventilation systems by increasing the number of particles in the operative ultra-clean area and hence the potential for infection.

## Methods and materials

Two orthopaedic operating theatres (one elective and one emergency theatre) were chosen as the site of the experiments. Both had ultra-clean cone of air ventilation systems (Howarth Ex flow 90) in place. The quality of the air is routinely tested on a regular bases

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to ensure it meets with the Health Technical Memorandum 2025 recommendations. Six separate tests were carried out: two tests were performed in the empty theatres, and four during standard orthopaedic operations (three hip replacements and one shoulder operation) with an identical full staff complement. A Casella slit sampler (Casella Co Ltd, London, England) was placed close to the middle of the operating table, inside the square canopy wall and 1 m off the floor, for air sampling at a rate of  $0.7 \text{ m}^3/\text{min}$  for 2 min. The blood agar plates (Columbia agar with horse blood, Oxoid) from the sampler were incubated at  $37^\circ\text{C}$  for 48 h. All samples were taken after the airflow had been running for at least 1 h. In each test the specialized perforated blanket was applied to the patient as recommended by the manufacturer. In the empty theatres the blanket was applied to the operative table. The operation of the slit samples was in the theatre only to switch it on and off.

### Samples

The following air samples were taken:

#### Control

Theatre completely empty before the start the operation. In the 'empty theatre' tests the theatre had no preceding operations or theatre staff present. For the tests where patients were present, theatre staff had been entering the theatre as part of the routine operating list.

#### Pre-warmer

Patients/table in the operating zone of the airflow system with the forced-air convection warmer applied but switched off. Patients draped for operation.

#### Warmer on

Fifteen minutes after the warmer was switched on.

#### Direct

One sample was taken directly from the air blower by connecting the hose to the air-sampling device.

#### Bacterial counts

Bacterial counts were calculated for each sample ( $\text{cfu}/\text{m}^3$ ).

**Table I** Results of air sampling in colony forming units per cubi meter ( $\text{cfu}/\text{m}^3$ )

Samples	Empty theatre	Warm system off	Warm system on
No patient (1)	0.00	1.25	0.00
No patient (2)	0.00	0.89	0.18
Mean	0.00	1.07	0.09
Patient (1)	2.1	1.4	3.6
Patient (2)	0.9	0.42	1.23
Patient (3)	2.0	4.6	5.9
Patient (4)	1.5	2.1	2.9
Mean	1.625	2.13	3.15

### Statistics

Results were compared using the Mann-Whitney *U*-test.

### Results

The results of the six tests are shown in Table I. Direct sampling from the air blower grew  $0.53 \text{ cfu}/\text{m}^3$ .

As the number of tests was small in this pilot study, limited statistical analysis was carried out in the patient group.

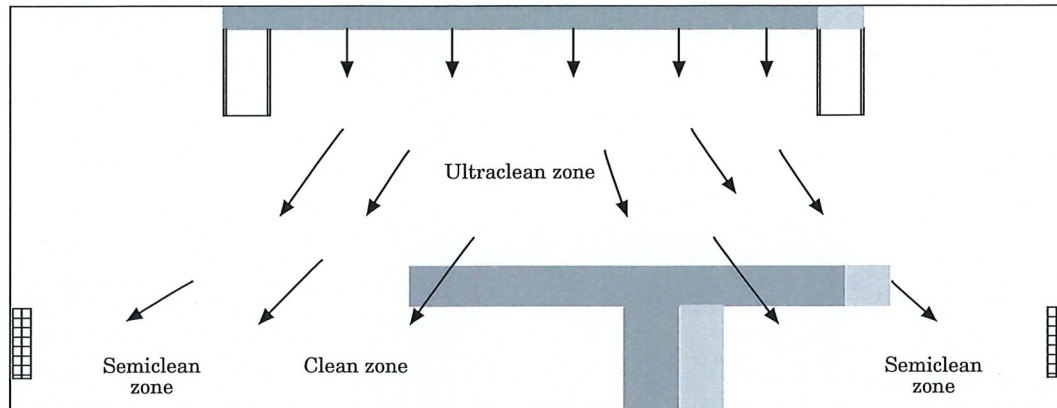
No patient tests showed a rise in colony forming units with the warming system off, followed by a fall with the system on.

Patient tests showed a nonsignificant rise in the number of colony forming units between the empty theatre and warmer off ( $P=0.88$ ) with a further rise in number of colony forming units between warmer off and warmer on ( $P=0.48$ ).

There was a difference between control samples and warmer on in the empty theatre and patient tests, but numbers were too small to enable statistical assessment of significance.

### Discussion

An ultra-clean ventilation system reduces the number of bacteria in the theatre air,<sup>1,2</sup> with the aim of reducing the incidence of surgical wound infection.<sup>3</sup> In laminar airflow theatres, airflow is produced in either a vertical or horizontal direction and they are equipped with high-efficiency particulate air (HEPA) filters. The cone of air ventilation systems used in this study supply an ultra-clean zone with high air velocity from the ceiling to the level of the operating table (operating zone). The surrounding area with a slower air velocity is referred to as the clean zone. The periphery of the operating theatre toward the air outlets is known as the semi-clean



**Figure 1** Zones in the ultra-clean cone of air ventilation system in operating theatres.

zone. Different air velocities result in airflow from the ultra-clean towards the clean and semi-clean zones (Figure 1).<sup>5</sup>

In our theatre, the heater air blower units are situated on the floor (clean zone), therefore, the airflow is reversed upwards into the ultra-clean zone. The main concerns leading to this study were, therefore, that normal airflow would be disrupted and organisms would be shed from the patients' skin due to the warm airflow over it.

In our study, a negligible number of colony forming units were grown directly from the air blower (0.53 cfu/m<sup>3</sup>). Avidan *et al.*<sup>6</sup> grew pathogenic organisms directly from the airstream of warming systems, which they concluded could be a source of hospital-acquired infection. However, they showed when warming systems were used in conjunction with a perforated blanket, had the microbial filter changed regularly and the hoses sterilized, the potential for contamination was reduced.

The differences we found between the control values of in-use theatre and empty theatre groups are likely to be due to the movement of the theatre staff. In the in-use theatre tests there had been prior staff movement because of the busy operating list, whilst the empty theatre tests were performed in a theatre that had been empty for some time.

The rise in counts seen in both groups, between control and warmer off-values, is likely to be explained by the disturbance of airflow created by staff movement, patient entry into theatre and the application of the blanket to both patient and table; the differences in the two will be related to the number of personnel in theatre.

In the empty theatre tests, counts fell between warmer off and warmer on as the disturbance to

airflow created by application of the blanket to the table was negated by the airflow system. Counts also confirmed the negligible number of colony forming units arising from the blower itself.

In the patient tests, counts were slightly higher with the warmer on, indicating that the warmer itself might produce a slight increase in the bacterial load. However, at no time did the average number of bacteria approach the maximum recommended (of 10 cfu/m<sup>3</sup>) for the ultra-clean air theatres.<sup>7</sup> This rise, therefore, is unlikely to be clinically significant, and the benefits of patient normothermia would appear to outweigh the theoretical disadvantages of warm air heaters in ultra-clean air theatres.

This study showed that use of warm air convection heaters on patients produced a small increase in the number of colony forming units in ultra-clean air theatres but the levels were unlikely to have clinical significance. By far the greatest effect on the number of colony forming units appeared to be the movement and presence of the patient and theatre staff in the theatre.

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## Research

## Open Access

**The Bair Hugger patient warming system in prolonged vascular surgery: an infection risk?**Joseph KC Huang<sup>1</sup>, Elizabeth F Shah<sup>1</sup>, Narayanan Vinodkumar<sup>1</sup>, MA Hegarty<sup>2</sup> and Robert A Greetorex<sup>3</sup><sup>1</sup>Surgical Registrar, Department of Surgery, Queen Elizabeth Hospital, King's Lynn, UK<sup>2</sup>Consultant Pathologist, Department of Microbiology, Queen Elizabeth Hospital, King's Lynn, UK<sup>3</sup>Consultant Surgeon, Department of Surgery, Queen Elizabeth Hospital, King's Lynn, UKCorrespondence: JKC Huang, [jkchuang@yahoo.com](mailto:jkchuang@yahoo.com)

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*Critical Care* 2003, **7**:R13-R16 (DOI 10.1186/cc1888)This article is online at <http://ccforum.com/content/7/3/R13>© 2003 Huang *et al.*, licensee BioMed Central Ltd (Print ISSN 1364-8535; Online ISSN 1466-609X). This is an Open Access article: verbatim copying and redistribution of this article are permitted in all media for any purpose, provided this notice is preserved along with the article's original URL.**Abstract****Introduction** Use of the Bair Hugger forced-air patient warming system during prolonged abdominal vascular surgery may lead to increased bacterial contamination of the surgical field by mobilization of the patient's skin flora.**Methods** This possibility was studied by analyzing bacterial content in air and wound specimens collected during surgery in 16 patients undergoing abdominal vascular prosthetic graft insertion procedures, using the Bair Hugger patient warming system. The bacterial colony counts from the beginning and the end of surgery were compared, and the data analyzed using the Wilcoxon matched pairs test.**Results** The results showed not only that there was no increase in bacterial counts at the study sites, but also that there was a decrease ( $P < 0.01$ ) in air bacterial content around the patient and in the operating theatre after prolonged use of the patient warmer. No wound or graft infections occurred.**Conclusion** The use of this warming system does not lead to increased bacterial contamination of the operating theatre atmosphere, and it is unlikely to affect the surgical field adversely.**Keywords** air microbiology, human, intraoperative care, operating rooms, surgical wound infection**Introduction**

Forced-air patient warming systems, such as Bair Hugger (Augustine Medical Inc., Eden Prairie, MN, USA), were developed in the 1980s and are acknowledged as being the most clinically effective patient warming modality [1,2]. The advantages of avoiding hypothermia for patients undergoing major surgical procedures are well established, and include decreased blood loss (with consequent reduction in blood product use) [3], wound infection [4], duration of intensive care and hospital stay [5,6] and cardiac ischaemia [7,8], and increased survival [6,9,10]. However, a potential disadvantage is the risk for bacterial contamination of the operating theatre environment. Prolonged exposure of the patient to the

exhaust of the warming blanket could potentially mobilize their resident skin organisms into the theatre atmosphere, and thence into the surgical field, possibly increasing the risk for prosthetic material infection. This has not previously been investigated.

We studied whether use of the Bair Hugger patient warming system increased bacterial contamination of the operating theatre and the surgical wound during prolonged surgery.

**Methods**

Sixteen consecutive patients undergoing aortic surgery with prosthetic graft insertion were prospectively studied. All vas-

cular surgery was performed in a standard positive pressure theatre. The Bair Hugger upper body blanket (model 522) was used for all patients. Bacteria sampling sites are shown in Fig. 1. Air samples were taken using standard techniques from the theatre atmosphere (sites A1–A3) and around the axillae (sites B1 and B2), where the exhaust air emerged, using the Biotest RCS centrifugal air sampler and Biotest Hycon TC agar strips (Biotest UK Ltd, Solihull, West Midlands, UK). A total of 160 l of air was sampled in 4 min from each of these sites. Sterile swabs were used to take specimens from the warming unit and hose (site C) and immediately plated onto standard blood agar culture media. Further specimens were taken from the wound edges with touch plates of blood agar (site D). Two readings were taken from each site, one when the warming blanket was first applied at the start of the operation and again at the end of the operation. All the culture media were then incubated at 36°C for 24 hours. The number of bacterial colonies visible to the naked eye on each of the agar strips and culture plates were then counted by hand and recorded.

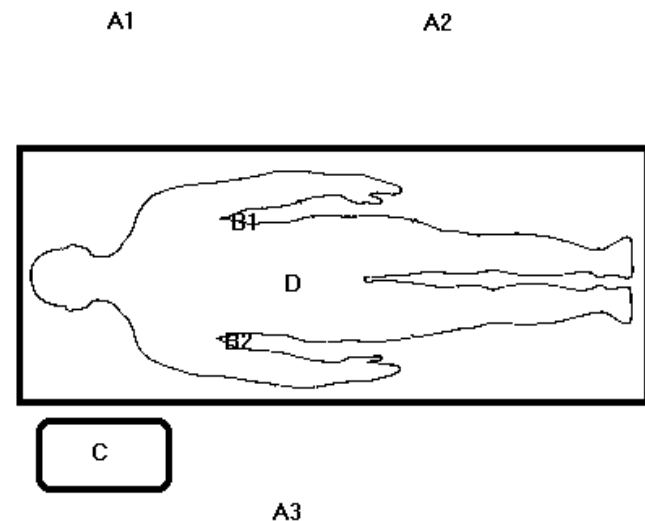
The duration of the operation was recorded. There were nine staff circulating in the operating theatre: three surgeons, two anaesthetists, one operating department assistant and three nurses. All patients had three doses of intravenous antibiotics perioperatively. The data were analyzed using the Wilcoxon matched pairs test [11].

## Results

Twelve male and four female patients were included in the present study. Their mean age was 72.5 years (range 60–86 years). The mean duration of use of the warming blanket was 234 min (range 180–270 min). From each site, the number of bacterial colonies at the start of surgery was compared with that at the end of the operation.

Results are shown in Tables 1 and 2. All operating theatre air specimens (sites A1–A3) exhibited a decrease in colony counts at the end of surgery (mean reduction 36.4%). The exhaust air (sites B1 and B2) colony counts also decreased at the end of surgery, although the size of the reduction was much less (mean reduction 9.5%). In the Wilcoxon matched

**Figure 1**



Sampling sites. A1–A3, room air; B1 and B2, exhaust from under drapes; C, hose and filter of warming unit; D, wound.

pairs test, the test statistic *T* equalled 0, because the rank difference was negative for all specimens from sites A1–A3, and B1 and B2. This indicates that there was a significant decrease in the colony counts at the end of surgery as compared with the beginning ( $P < 0.01$ ). All filter (site C) and wound specimens (site D) were sterile.

None of the patients developed postoperative wound or prosthetic infections during a 6-month follow-up period.

In the present study bacteria were not typed; only the absolute numbers of colonies cultured were counted. Typing was to be done only if there was an increase in colony counts at the end of surgery, and this did not occur in any of the patients studied.

## Discussion

As indicated above, the benefits of maintaining normothermia in surgical patients is well documented. It has been shown

**Table 1**

### Comparison of the mean number of colonies

Site (see Fig. 1)	Mean number of colonies		Mean change
	Start of operation	End of operation	
Operating room air (A1–A3)	112.9 (82–296)	71.7 (62–162)	36.4% reduction
Exhaust (B1 and B2)	31.6 (22–90)	28.6 (15–86)	9.5% reduction
Hose/filter (C)	0	0	–
Wound (D)	0	0	–

**Table 2****Comparison of colony numbers**

Patient number	Number of bacterial colonies at different sites (see Fig. 1)					
	Room air (A1–A3)			Exhaust (B1 and B2)		
	Pre	Post	Change	Pre	Post	Change
1	112	71	–41	29	27	–2
2	102	62	–40	32	30	–2
3	99	70	–29	24	22	–2
4	98	73	–25	22	21	–1
5	97	62	–35	27	25	–2
6	120	67	–53	25	23	–2
7	89	63	–26	37	25	–12
8	129	73	–56	24	22	–2
9	124	68	–56	27	23	–4
10	296	141	–155	90	86	–4
11	98	70	–28	30	24	–6
12	82	63	–19	31	30	–1
13	96	66	–30	22	20	–2
14	91	64	–27	28	25	–3
15	90	68	–22	31	29	–2
16	83	66	–17	27	26	–1

that the warming equipment itself does not cause bacterial dispersal [12] but the role of patient flora was not investigated and the study was not conducted in a true surgical setting. This remained a concern in our unit, especially because some bacteria in wound infections originated from the patients' skin [13]. The present study did not show any increase in the mobilization and dispersal of patient resident skin organisms. The exhaust air from beneath the surgical drapes, which had passed over the patient's skin, showed a decrease in the number of bacterial counts at the end of surgery, and this demonstrated that there was no increase in air contamination associated with the Bair Hugger patient warming system. Furthermore, it indicated that the warm air stream did not force circulation of the patients' skin organisms. If the Bair Hugger were affecting the atmosphere adversely, then the room air counts would also be expected to increase rather than decrease. In fact, the colony numbers in room air and system exhaust were reduced and this was consistent.

Although the study was not designed to evaluate other causes of bacterial presence in the operating theatre, we feel that the higher count at the beginning of surgery in room air may be due to the unrestricted movement of personnel in and out of the operating room, with opening and closing of doors,

leading to increased air flow and turbulence. Toward the end of surgery, movement of staff is much less and this may explain the fall in bacterial counts seen as the air turbulence decreases [14,15].

## Conclusion

We conclude that the use of the Bair Hugger patient warming system during prolonged abdominal surgery does not lead to increased bacterial contamination of the operating theatre atmosphere, and it is therefore unlikely to cause contamination of the surgical field.

## Competing interests

None declared.

## Key messages

- Forced-air warming does not force patient's resident skin organisms into and contaminate the operating theatre atmosphere
- Such systems are unlikely to increase the incidence of wound and prosthetic infections

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# **EXHIBIT DX67**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS



# Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infection?

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## KEYWORDS

Bair Hugger system;  
Nosocomial infection;  
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Thermoregulation

**Summary** Various reliable body heat-regulating systems have been designed and developed with the aim of maintaining an adequate body temperature in the course of major surgery. This is crucial to avoid the onset of potentially severe complications that are especially serious in elderly and debilitated subjects. Among these systems, the Bair Hugger blanket has demonstrated excellent efficacy. However, some reports in the literature have suggested that the use of such devices can increase the risk of nosocomial infections, particularly surgical wound infections. The aim of this study was to assess the risk of contamination of the surgical site correlated to the use of the Bair Hugger blanket during hip replacement surgery. To this end, the level of bacterial contamination of the air in the operating theatre was quantified with and without the use of the Bair Hugger, during the course of 30 total non-cemented hip implants performed in patients with osteoarthritis. Sampling was done both in the empty theatre and during surgical procedures, in different zones around the operating table and on the patient's body surface. Statistical analysis of the results demonstrated that the Bair Hugger system does not pose a real risk for nosocomial infections, whereas it does offer the advantage of preventing the potentially very severe consequences of hypothermia during major orthopaedic surgery. In addition, monitoring patients over the six months following the

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operation allowed us to exclude a later manifestation of a nosocomial infection.

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## Introduction

A number of studies have demonstrated that a drop in body temperature, especially during major surgery, can cause potentially dangerous complications, particularly in the elderly and debilitated, or in those with pre-existing disease.<sup>1,2</sup> Nosocomial infections are a particular problem, adversely affecting the postoperative course in terms of patient morbidity, longer hospital stay and higher associated costs for the healthcare facility.<sup>3–7</sup>

To guarantee the maintenance of an adequate body temperature, a number of different regulation systems with proven efficacy have been designed and developed.<sup>8,9</sup> Among these is the Bair Hugger system (Augustine Medical Inc., Eden Prairie, MN, USA), that consists of a temperature management unit comprising a heat generator, a blower to circulate the heated air and a temperature control system equipped with various sensors. This unit is connected by a rubber tube to a blanket that is heated by circulating warm air, thus maintaining the surface temperature of the body underneath it within a physiological range.<sup>10,11</sup>

Some reports in the literature, however, have suggested that such body-warming devices could themselves pose a risk factor for perioperative nosocomial infections, especially at the surgical wound site.<sup>12–16</sup> The aim of this study was to assess the infective risk associated with the use of such devices during hip replacement surgery. We studied the levels of bacterial contamination in the operating theatre potentially associated with the use of the Bair Hugger.

## Methods

To assess the infective risk potentially correlated with the use of the Bair Hugger body-warming system, the levels of bacterial contamination present in the air in the operating theatre were monitored with and without the use of the forced-air warming blanket.<sup>17,18</sup>

The air sampler used was an Active Surface Air System (SAS; Aquaria, s.r.l, Italy), a single plate sampling system that directs a constant flow of air on to an agar plate, and which meets the ISO

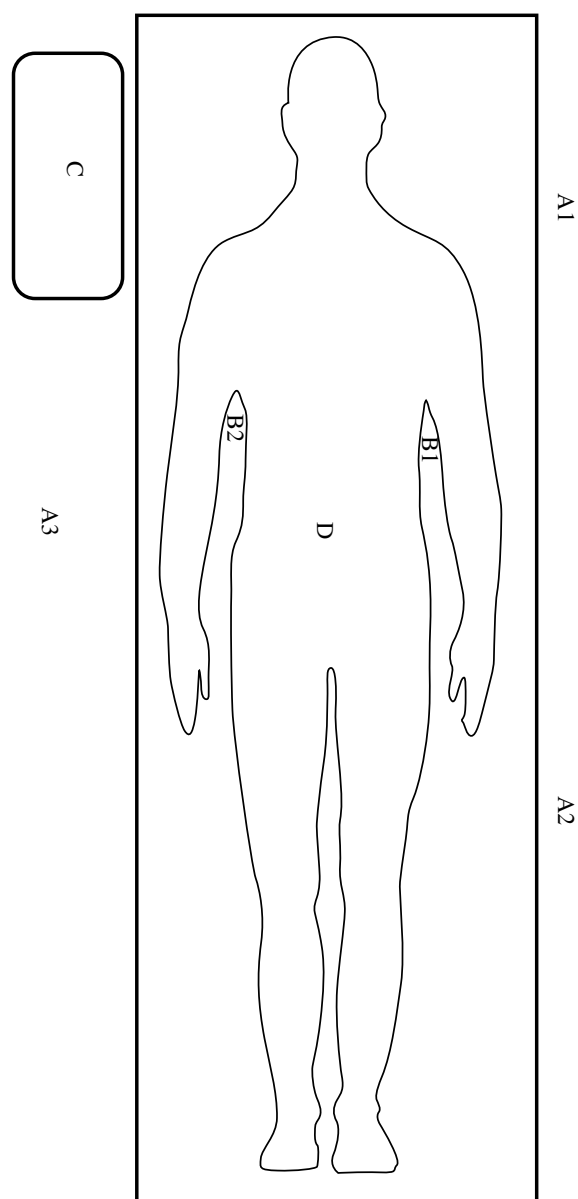
14698-1 standard. The efficacy of the device is evaluated on the basis of the cut-off size ( $d_{50}$ ), i.e. the minimum diameter of the particles selected by the sampler. Pasquarella *et al.*, in a recent review, reported the different cut-off size of some air samplers as ranging from 0.58  $\mu\text{m}$  (Andersen Cascade Impactor, stage n.6) to 7.5  $\mu\text{m}$  (Reuter Centrifugal Sampler).<sup>19</sup> The SAS has a  $d_{50}$  of 1.5  $\mu\text{m}$ , implying a good level of efficacy; it is particularly suitable for studying air where there may be low concentrations of organisms, such as in hospital environments.<sup>19–22</sup> Moreover, despite the greater efficacy of the Andersen sampler, Morris *et al.* recommended the use of the SAS device because of its being so practical and reliable when used in epidemiological studies and during outbreak investigations in hospital environments.<sup>23</sup>

The air was blown at a flow rate of about 90 L/min onto 55 mm Petri dishes containing Plate Count Agar culture medium to quantify the total bacterial load; Mannitol salt agar (MSA), Wurtz and Sabouraud agars (all agars supplied by Biolife Italiana s.r.l, Milan, Italy) to make a qualitative assessment of any organisms found. After sampling, the plates were incubated at 36 °C in air for 48 h before counting and identifying any potentially pathogenic micro-organisms.

The bacterial counts were expressed as cfu/m<sup>3</sup> (colony-forming units per square metre of air).

Sampling was done during total non-cemented hip implantations performed on 30 female patients with osteoarthritis, with a mean age of 64 years (range: 58–71). All procedures were performed at the Bari University Hospital, Italy. In 20 of the subjects, a Bair Hugger blanket was placed on the operative couch, and used for an average period of about 90 min. As suggested by Huang *et al.*, sampling was done for all the procedures, both at rest, when the theatres were empty and not being used, and under operational conditions, in three different points (A1, A2 and A3) around the operating table, as shown in Figure 1 and at two different times (prior to patient placement on the table, and at the start of the procedure).<sup>13</sup>

In the 20 cases in which the Bair Hugger was used, sampling was also carried out during the course of the operating procedures. For these subjects, environmental sampling was done in



**Figure 1** Air sampling points. (Redrawn from Huang *et al.*<sup>13</sup> by kind permission.)

the zones around the axillae, where the air emerged (B1 and B2, Figure 1) and in the zone around the blower (tube and heating unit filter). Samples were also taken from the patient using sterile buffers on the skin surface to be incised, before disinfecting the skin, and in the same way on the same area at the end of the procedure.

To reveal any significant variations among the three sampling points of the operative site (A1, A2, A3, Figure 1) analysis of variance was performed; the alpha level of significance was set at  $P < 0.05$ . Statistical analysis of the environmental samples was done using the SAS statistical software package (SAS Institute Inc., Carolina, USA). All patients were

monitored for a further six months to check for late onset of nosocomial infection.

## Results

Under the at-rest conditions in the empty theatres, no significant differences were observed among the mean values of the bacterial loads measured at the three different points around the operative site ( $A1 = 17.8 \pm 14.5$  cfu/m<sup>3</sup>;  $A2 = 19.4 \pm 17.5$  cfu/m<sup>3</sup>;  $A3 = 19.2 \pm 17.7$  cfu/m<sup>3</sup>;  $F = 0.09$ ,  $P > 0.05$ ). In all three points, however, a significant increase in the mean bacterial load was observed under operational conditions, immediately after placing the patient on the operating table ( $A1 = 79.2 \pm 52.2$  cfu/m<sup>3</sup>,  $F = 38.54$ ,  $P < 0.001$ ;  $A2 = 61.2 \pm 38.8$  cfu/m<sup>3</sup>,  $F = 28.92$ ,  $P < 0.001$ ;  $A3 = 69.1 \pm 56.8$  cfu/m<sup>3</sup>,  $F = 21.09$ ,  $P < 0.001$ ; Figure 1).

In the 20 procedures in which the Bair Hugger was used, the mean bacterial load values were significantly increased in the three points compared with the at-rest conditions ( $A1 = 41.7 \pm 28.1$  cfu/m<sup>3</sup>,  $F = 15.6$ ,  $P < 0.001$ ;  $A2 = 42.2 \pm 28.6$  cfu/m<sup>3</sup>,  $F = 12.2$ ,  $P = 0.001$ ;  $A3 = 42.3 \pm 28.2$  cfu/m<sup>3</sup>,  $F = 12.62$ ,  $P < 0.001$ ; Figure 1). However, in point A1 there was a significant reduction of the mean bacterial load values between the moment in which the patient was placed on the operating table and after the use of the Bair Hugger ( $F = 8.62$ ,  $P < 0.05$ ; Figure 2).

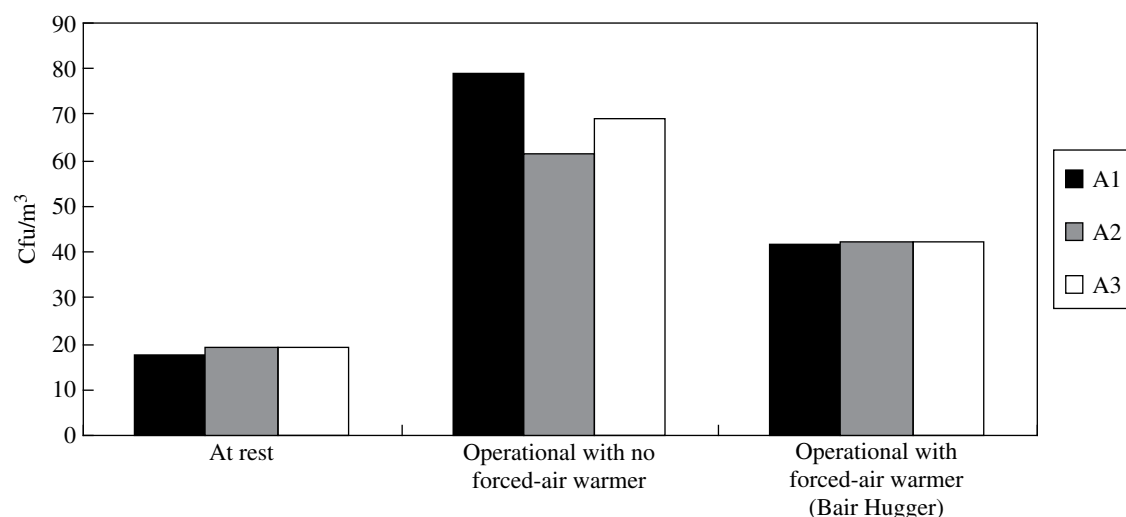
The mean bacterial load recorded during the 20 procedures in which the full body forced-air warming system was employed was  $36.8 \pm 24$  cfu/m<sup>3</sup> around the right axilla,  $42.7 \pm 38.8$  cfu/m<sup>3</sup> around the left axilla and  $45.1 \pm 39.8$  around the forced-air blower.

Fungal contamination was uncommon; *C. parapsilosis* was found on the non-disinfected skin of one patient, and *Aspergillus flavus* was found in the air rising around the axilla of another subject.

All the subjects in this study had an uncomplicated postoperative course, free from surgical wound infection, and from systemic complications such as cystitis or bronchopneumonia.

## Discussion

Lee *et al.* demonstrated that measurements from different active air samplers may not be directly comparable, despite a comparison of three sampling devices, collecting simultaneous samples, showing high linear correlations between methods.<sup>24</sup> The same evidence is underlined in the CDC guidelines for environmental infection control in healthcare facilities.<sup>25</sup> Perioperative



**Figure 2** Mean bacterial load (cfu/m<sup>3</sup>) in the three sampling points in at-rest and operational conditions and after placement of the forced-air blanket.

hypothermia is a common phenomenon, associated with physical factors such as exposure of patient to the operating theatre ventilation system and the infusion of cold solutions, but more importantly to anaesthesia-induced alterations on the individual's thermal homeostasis mechanisms.

Within the first hour of induction, both general and local anaesthetics act on the sympathetic system, inhibiting peripheral vasoconstriction and causing a redistribution of the heat from the body core to the periphery. In addition, the reflex shivering mechanism can be diminished, especially if there is associated administration of muscle relaxants.<sup>26</sup> The Bair Hugger blanket is considered to be among the most effective systems for achieving and maintaining a correct perioperative regulation of body heat.<sup>27,17,28</sup> It exploits the active warming principle, transferring the warmth of the inner circulating heated air to the patient's body surface, by convection.<sup>9</sup>

The Bair Hugger is not indicated in surgical situations that cannot offer a sufficient skin-blanket coverage area to maintain adequate body heat, including liver transplantation, major abdominal surgery, patients with multiple trauma, etc.<sup>11,29</sup> When it can be used, the system has the advantages of being non-invasive, cheap and simple to use, and above all effective. In our study, no patient developed any of the complications of hypothermia described in the literature, such as hypertension, myocardial ischemia, ventricular tachycardia, haemorrhage resulting from alterations of the platelet function and the activity of some enzymes involved in the clotting cascade, or local or general infections associated with cold-induced skin vasoconstriction.<sup>1,2,30</sup> The latter induces a reduced

oxygen tension in subcutaneous tissues, rendering them more susceptible to microbial invasion and to neutrophil oxidation-induced inhibition of lymphocyte antibody formation and killing functions.<sup>3</sup>

The role of the forced-air body blanket as a potential source of infection is still controversial. Avidan *et al.* demonstrated a higher airborne bacterial load in the air samples analysed, and a higher incidence of nosocomial infections in patients kept warm using the Bair Hugger.<sup>12</sup> More recent studies, however, have not found a significant increase in the bacterial load in the operating theatre attributable to use of the system;<sup>13</sup> whereas other studies that did report such an increased bacterial load did not find an associated significant increase in the frequency of nosocomial infections.<sup>31</sup>

The results of this study seem to point to the same conclusion. In none of the surgical patients did a nosocomial infection develop. Although a significantly increased bacterial load was recorded both after the patient's entry into the operating theatre ( $P < 0.001$ ) and after placement of the body-warming system at all the sampling points, not one patient in this study developed a nosocomial infection. There was also a statistically significant difference in airborne bacterial load during operations in which the blanket was or was not used. In any case, in two of the sampling points (A2 and A3) no significant differences ( $P > 0.05$ ) were observed between the two increases, although the mean bacterial load was numerically lower (Figure 2) after application of the Bair Hugger than immediately after placement of the patient on the operating table. Indeed, at sampling point A1, the increase in the bacterial load seemed to be significantly lower ( $P < 0.05$ )

between the moment in which the patient was placed on the operating table and after use of the body-warming system.

In light of the results reported here, the Bair Hugger system does not seem to pose a real risk of nosocomial infections, while it does offer the advantage of preventing the potentially grave consequences induced by hypothermia during major orthopaedic surgical procedures. The increased bacterial load found after application of a body-warming system appears to be comparable to, or lower than, the load present at the time of placement of the patient on the operating table. This provides further confirmation of the literature data supporting the contention that the main potential contamination factor in the operating theatre is the presence of the theatre medical staff themselves, their movements, and in general their behaviour.

Our study has some limitations. The sample size of patients was small for the calculation of the statistical incidence of surgical site infection after the use of the Bair Hugger. Further studies are needed to determine the security of this active warming system. Besides, it is evident that the operating theatre personnel themselves play an active role in introducing potential nosocomial pathogens into the environment. This variable is not easily quantifiable.

#### Conflict of interest statement

None declared.

#### Funding source

University of Bari.

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# **EXHIBIT DX68**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS

# Brief Communication Communication brève

## Evaluation of bacterial contamination on surgical drapes following use of the Bair Hugger® forced air warming system

Lindsay L. Occhipinti, Joe G. Hauptman, Justin J. Greco, Stephen J. Mehler

**Abstract** — This pilot study determined the rate of bacterial contamination on surgical drapes of small animal patients warmed intra-operatively with the Bair Hugger® forced air warming system compared to a control method. Surgical drapes of 100 patients undergoing clean surgical procedures were swabbed with aerobic culturettes at the beginning and end of surgery. Samples were cultured on Trypticase soy agar. Contamination of the surgical drapes was identified in 6/98 cases (6.1%). There was no significant difference in the number of contaminated surgical drapes between the Bair Hugger® and control groups ( $P = 0.47$ ).

**Résumé** — Évaluation de la contamination bactérienne des champs opératoires après l'utilisation du système de chauffage à air pulsé Bair Hugger<sup>MD</sup>. Cette étude pilote a déterminé le taux de contamination bactérienne des champs opératoires de patients petits animaux réchauffés lors du processus peropératoire à l'aide du système de chauffage à air pulsé Bair Hugger<sup>MD</sup> comparativement à une méthode témoin. Les champs opératoires de 100 patients subissant des interventions chirurgicales propres ont été écouvillonnés avec des Culturettes aérobies au début et à la fin de la chirurgie. Les échantillons ont été cultivés sur gélose Trypticase soja. La contamination des champs opératoires a été identifiée dans 6/98 cas (6,1 %). Il n'y avait aucune différence significative dans le nombre de champs opératoires contaminés entre le groupe Bair Hugger<sup>MD</sup> et le groupe témoin ( $P = 0,47$ ).

(Traduit par Isabelle Vallières)

Can Vet J 2013;54:1157–1159

**H**ypothermia is commonly encountered as a sequel to general anesthesia in veterinary small animal surgical patients (1). Maintenance of normothermia during anesthesia reduces rates of surgical site infection, reduces mortality, and decreases the length of hospital stay in human surgical patients (2,3). The Bair Hugger® forced air warming device was developed in 1987 originally to warm patients during the post-operative period. It is now widely used in human and veterinary anesthesia to maintain normothermia during the perioperative period. In veterinary medicine, the Bair Hugger® has been shown to be effective in maintaining patient temperature within 2°C to 4°C of normal during anesthesia (4). In a comparison

of 4 intraoperative warming devices, forced air warming was shown to be effective at maintaining patient temperature, second only to a group warmed by an electric heating pad and warm water bottles (1). Although accepted to be an effective measure to maintain normothermia, controversy exists as to whether forced air warming systems increase the risk for surgical site infection (5–7).

To the authors' knowledge, there are no studies in veterinary medicine that evaluate surgical site contamination from use of the Bair Hugger® forced air warming system. The goal of this study was to compare the rates of bacterial contamination on the surgical drapes of small animal patients with and without the use of the Bair Hugger® forced air warming system. The null hypothesis was that there would be no significant difference in the frequency of contaminated surgical drapes when the Bair Hugger® system was used compared to the control method for intraoperative warming.

One hundred canine patients undergoing clean surgical procedures were enrolled into the study between September of 2011 and March of 2012. Patients were randomly assigned to the Bair Hugger® (BH) group or the control group (CTL) using a coin toss. Patients were excluded if they weighed less than 5 kg, had evidence of pyoderma, or were receiving concurrent antibiotic therapy. Patient samples were excluded from analysis if the pre-operative samples were positive for bacteria.

The study group patients were warmed intraoperatively with the BH forced air system and a circulating warm water blanket placed beneath the patient. Each patient in the BH group

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**Table 1.** Contamination in relation to types of surgical procedures performed

Surgery type	Total number	Number Bair Hugger®	Number control	Contamination Bair Hugger®	Contamination control
Orthopedic	76	46	30	4	2
Soft tissue	13	4	9	0	0
Neurological	9	8	1	0	0

received a new Bair Hugger® perforated blanket at the beginning of anesthesia. One of 3 blanket models (55577, 53777, 53077, Arizant Health Care, Eden Prairie, Minnesota, USA) was used. The blanket model that covered the largest amount of non-clipped body surface area was chosen for each patient. Blankets were placed over each patient prior to final preparation of the surgical site. Two forced air units (model 505; Arizant Health Care), were designated to the operating suites and rotated among 3 operating rooms. A new filter was placed in each device prior to the beginning of the study. Patients in the control group were warmed intraoperatively by a circulating warm water blanket placed beneath the patient and with 3 warm water bottles heated to 41°C.

The patients were positioned in dorsal, lateral, sternal, or dorsolateral oblique positioning and draped routinely as required for the procedure being performed. An antimicrobial surgical incise drape (Ioban 2; 3M company, St. Paul Minnesota, USA) was used over the surgical site at the preference of the attending surgeon. After patient drapes were in place, dry, sterile rayon-tip swabs (BBL CultureSwab; Becton, Dickinson and Company, Sparks, Maryland, USA) were used to swab the surgical drapes. Swabbing was initiated from the margin of the paper or antimicrobial incise drape adjacent to the incision and continued laterally 6 cm and circumferentially around the surgical site. This sample was designated as the pre-operative sample (PRE) and was collected immediately prior to skin incision. For BH samples, the PRE sample was collected prior to turning the BH unit on. The surgical procedure was then performed routinely. A second sample swab was obtained as described for the PRE sample after placement of the last skin suture or staple. This sample was designated as the post-operative sample (PST). Immediately after collection, the sample swabs were cut mid-shaft with sterile mayo scissors and placed into sterile red top tubes containing 4 mL of sterile saline. Samples were then plated with a calibrated 1 µL loop (#3730, Science Center, Santa Fe, New Mexico, USA) onto combination plates of Trypticase soy agar with 5% sheep blood and MacConkey agar (#221289, Trypticase Soy Agar plates; Becton, Dickinson and Company). All samples were plated within 1 h of collection when possible. If a delay to plating was anticipated, then samples were refrigerated at 2°C to 4°C within 1 h of collection until plating was done. All samples were plated within 14 h of collection. Plates were incubated for 48 h at 35°C to 37°C. Bacterial growth was recorded as number of colonies formed. Bacterial identification to the genus level was performed on samples positive for bacterial growth.

Contamination of the surgical drape was defined as a positive bacterial culture from the PST culture swab.

The response variable in our study was bacterial contamination. The factors that could affect contamination were: method of intraoperative warming (BH or CTL), patient variables (age, weight, gender), patient positioning, type of procedure performed (orthopedic, soft tissue, or neurological), surgeon, number of surgeons (1 to 2 or 3+), number of total operating room personnel (1 to 5 or 6 to 9), operating room used, total anesthesia time, patient temperature at start and end of anesthesia (> 36.6°C or < 36.6°C), total surgical time, and the use of an antimicrobial incise drape on the surgical site. Univariate Chi-square testing was used to determine if the surgeon or operating room used had an effect on contamination. Any association of all other factors on contamination was quantified by means of multiple logistic regression. Multicollinearity was assessed by means of variance inflation factor (VIF); all VIF were < 2.5. Linearity was assessed by means of the Box Tidwell approach; age and body weight (kg) failed the linearity assumption and were transformed to binary variables. All variables were initially entered into the logistic equation and deleted according to highest *P*-value. Univariate analysis was also performed to determine if any factor was significantly associated with contamination. The Wilcoxon rank sum test was used to determine if there was a significant difference between bacterial counts in the BH and CTL population. Significance was set at *P* < 0.05.

One hundred canine patients were enrolled into the study. Samples from 2 patients were excluded from analysis due to positive bacterial culture on the PRE sample. Samples from 98 patients were used for statistical analysis.

Contamination of the surgical drapes occurred in 6/98 cases (6.1%). Contamination of the surgical drapes occurred 4 times in the BH group and 2 times in the CTL group (Table 1). There was no significant difference in the number of contaminated surgical drapes between the BH and CTL groups (*P* = 0.47). There was no significant difference in the bacterial colony counts between the BH and CTL groups (*P* = 0.35). Patient variables of age, weight, and gender had no significant effect on contamination (*P* = 0.13, 0.38 and 0.73, respectively). The variables of patient positioning, type of procedure performed, and number of scrubbed personnel had no effect on contamination (*P* = 0.94, 0.97, and 0.49, respectively). Additionally, total anesthesia time and the use of an antimicrobial incise drape also had no significant effect on contamination (*P* = 0.82, 0.30). Bacteria identified from contaminated samples included *Staphylococcus* from 5 samples and *Micrococcus* from 1 sample.

The overall incidence of contamination of the surgical drapes was 6.1%. There was no significant difference between the frequency of contamination or the bacterial colonies grown in the BH or CTL groups. Additionally, no patient or environmental

factors were significantly associated with contamination of the surgical drapes. The most common bacterial contaminant was *Staphylococcus* which was found in 5 of 6 cases. These bacteria are likely to be normal flora from the patient skin and hair follicles or could represent contamination from human personnel. *Micrococcus* was noted in 1 case and likely originated as a contaminant from the patient's skin or dirt residing on the patient's hair coat.

Limitations of this study include the small number of samples that were positive for contamination, potentially creating a type II error. Additionally, the low incidence of positive samples in our study may due to the low sensitivity of bacterial detection, set at 4000 colony-forming units per sample swab. Further studies with larger sample sizes are warranted to further investigate rate of contamination with the BH forced air warming system. In addition, future studies should focus on less sample dilution and plating of a larger sample volume for a higher sensitivity in detecting contamination.

In conclusion, the overall incidence of bacterial contamination of the surgical drapes in our study was low (6.1%). We did not detect a significant difference in bacterial contamination of surgical drapes with use of the BH compared to the control. The

clinical relationship between contamination of surgical drapes and surgical site infection (SSI) is unknown and beyond the scope of this study. Further studies with larger sample sizes are warranted to investigate the risk of surgical site contamination with forced air warming devices.

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# **EXHIBIT DX69**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS



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## Journal of Clinical Anesthesia



Original contribution

# Airborne bacterial contamination during orthopedic surgery: A randomized controlled pilot trial



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## ABSTRACT

**Study objective:** Several factors such as lack of unidirectional, turbulent free laminar airflow, duration of surgery, patient warming system, or the number of health professionals in the OR have been shown or suspected to increase the number of airborne bacteria. The objective of this study was to perform a multivariate analysis of bacterial counts in the OR in patients during minor orthopedic surgery.

**Design:** Prospective, randomized pilot study.

**Setting:** Medical University of Vienna, Austria.

**Patients:** Eighty patients undergoing minor orthopedic surgery were included in the study.

**Interventions:** Surgery took place in ORs with and without a unidirectional turbulent free laminar airflow system, patients were randomized to warming with a forced air or an electric warming system.

**Measurement:** The number of airborne bacteria was measured using sedimentation agar plates and nitrocellulose membranes at 6 standardized locations in the OR.

**Main results:** The results of the multivariate analysis showed, that the absence of unidirectional turbulent free laminar airflow and longer duration of surgery increased bacterial counts significantly. The type of patient warming system and the number of health professionals had no significant influence on bacterial counts on any sampling site.

**Conclusion:** ORs with unidirectional turbulent free laminar airflow, and a reduction of surgery time decreased the number of viable airborne bacteria. These factors may be particularly important in critical patients with a high risk for the development of surgical site infections.

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## 1. Introduction

Surgical site infections (SSIs) are among the most severe complications in orthopedic and trauma surgery and have a serious impact on patient morbidity and mortality. Despite strict perioperative hygiene standards the incidence of postoperative orthopedic wound infections is still high ranging between 0.1% to 12% [1–3].

The infected surgical wound is usually colonized by commensal bacteria originating from the patient's own skin (endogenous) or exogenously by bacteria airborne in the operating room (OR). While there is general agreement on the protective effect of adequate skin antisepsis on the rate of SSIs, strategies to reduce airborne contamination are still disputed. One possibility for reducing airborne contamination is the use of a unidirectional

turbulent free laminar airflow ventilation system (laminar airflow). Surprisingly, while the benefit of laminar airflow systems seems intuitive, evidence to implement laminar airflow as a standard requirement for every OR is contradictory [4,5]. As laminar airflow is costly and conclusive evidence is lacking, many hospital administrators hesitate to implement laminar airflow technologies in their ORs. In the US only 30% of 256 hospitals in 4 US states reported the regular use of laminar airflow in 2005 [6].

However, also other factors such as duration of surgery, number of OR staff [7] and use of forced air patient warming [8] might influence airborne bacterial displacement and could blur eventual beneficial effects of laminar airflow.

The aim of the study was thus to determine the influence of four intraoperative factors – use of laminar airflow, duration of surgery, number of health professionals present and use of forced air – on airborne bacterial contamination, measured by 6 sedimentation plates at standardized locations in the OR including two locations on the instrument table.

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### Abbreviations

OR	Operating room
SSI	Surgical site infection
Laminar airflow	Laminar airflow ventilating system
CFU	Colony forming unit

## 2. Materials and methods

The study was approved by the Ethics Committee of the Medical University of Vienna and patients' written, informed consent was obtained in all patients undergoing minor orthopedic interventions either the day before surgery or on the day of surgery, if the patient had not been admitted to the hospital on the day before surgery, from January 2009 to June 2009. A manuscript using the same study patients' data as this paper demonstrated that different laminar airflow sizes affected the bacterial count on the instrument table [9]. In the present study bacterial counts on *all* positions were analyzed with multivariate methods, including the factor "patient warming system". Patients were randomized with excel random numbers to intraoperative warming with either a BairHugger forced air upper-body warming blanket (Arizant, Eden Prairie, MN) or a HotDog upper-body electric blanket (Augustine Biomedical + Design, Eden Prairie, MN) after induction of anesthesia. Randomization was performed by a medical student not involved with the study proceedings and delivered via opaque envelopes. Patients had to meet the following inclusion criteria: Age between 18 and 90 years, a BMI of 20–30, surgery lasting at least 1 h (expected).

A single observer (R.O.) present during each intervention monitored the following parameters: Number of health professionals present in the OR (maximum), duration of surgery (from skin incision to last suture), presence of a laminar airflow, and method of patient warming (forced air versus electric polymer blanket).

### 2.1. Measurements

Number of airborne bacteria was assessed by positioning four agar plates (90 mm diameter) in the OR and two nitrocellulose membranes (47 mm diameter) directly on the sterile instrument table. The first agar plate (plate 1) was positioned 15 cm above floor level, the second (plate 2) at table level, the third (plate 3) at 150 cm (plates 1–3 behind the surgical draping at the side of the anesthesiologist), and the fourth (plate 4) at table level with a distance of approximately 50 cm to the sterile operating field (on the surgical side of the draping). The nitrocellulose membranes (plates 5, 6) were both placed at the instrument table adjacent to each other (Fig. 2).

The agar plates and the nitrocellulose membranes were collected at the end of the surgical intervention. The nitrocellulose membranes were transferred to agar plates. All plates were then incubated for 48 h at 36°. After incubation the colony forming units (CFUs) were counted. The results were analyzed in CFU/m<sup>2</sup>/h to adjust for OR size.

## 3. Statistical analysis

All values are displayed as means  $\pm$  standard deviation, median (25th–75th quartile) or frequency (%), as appropriate. Plates 5 and 6 were averaged before analysis. Sample size was estimated with bacterial growth on the instrument table plates (mean of plates 5 & 6) as primary outcome. With an alpha error of 0.05, a power of 0.8 and an effect size of 0.7 for difference of airborne contamination by non-forced air warming versus forced air warming, 40 patients per group were calculated for a Wilcoxon-Mann-Whitney test as primary analysis. This simplified model was used to calculate the sample size estimate, since not enough previous knowledge about the possible relation of the

main parameter of interest and airborne bacterial contamination was available.

Due to the skewed nature of bacterial growth data a generalized linear model with gamma distribution and log-link was used to analyze influence of time, number of health professionals, presence of laminar airflow and type of patient warming system on the number of viable bacteria at the different locations as secondary analysis. A QQ-Plot was performed to assess adequacy of assumption of distribution, which proved to be applicable.

G\*Power (Duesseldorf, Germany) was used for sample size estimation; SPSS 23.0 (IBM, Armonk, NY, USA) was used for statistical analysis. A  $p < 0.05$  was considered statistically significant.

## 4. Results

All patients completed the study. The average age of patients was  $43 \pm 15$  years, with a weight of  $78 \pm 15$  kg and a height of  $174 \pm 9$  cm. 44 male (55%) and 36 female (45%) patients were included (see Fig. 1). Details about surgical interventions, number of health professionals present, duration of surgery, the use of forced air or electric blanket warming and laminar airflow are displayed in Table 1.

There was no difference for bacterial growth on the mean of plates 5 & 6 between the forced air and the non-forced air warming group ( $p = 0.6$ , Wilcoxon-Mann-Whitney test). Results of the multivariate model indicate, that a longer duration of surgery increased bacterial count on plates 1 to 4 and absence of laminar airflow increased bacterial count on plates 1 to 6 significantly (Table 2). There was a trend, that longer duration of surgery increased bacterial count on plates 5 & 6 ( $p = 0.07$ ) as well. There was no difference for forced air versus resistive warming for bacterial count on either plate. A reduced model without patient warming method did not change any significances discovered in the extended model.

In a follow-up of all patients until hospital discharge (range 0–4 days), no SSIs were reported.

## 5. Discussion

In the present study we found, that the absence of laminar airflow and a longer duration of surgery increased airborne bacteria in the OR. In patients with a high risk for surgical wound infections, optimization of these factors may be an important preventive measure.

Despite being widely used the benefits of laminar airflow environments in ORs are still disputed. While the concept of clean, laminar flowing air to avoid SSIs is plausible and supported by some studies, other authors disagree as they were not able to demonstrate any beneficial effect of laminar airflow systems [4–6,10,11]. According to the present study other factors may be just as important as the availability of a laminar airflow system, e.g. a longer duration of surgery might completely annihilate the contamination-reducing effects of laminar airflow.

Particularly number of health professionals in the OR may be an important factor to consider when reducing airborne contamination, [7] however this effect could not be reproduced in our study, possibly due to the limited number of patients.

As mentioned the duration of surgery is in our study a very influential factor determining the amount of bacterial sedimentation. However, this factor itself obviously is dependent again on a number of other factors, which may not all be equally optimizable: the skill of the surgeon, type of surgery, OR management, patient's surgical site and others [12, 13].

An important finding of our study was that the type of patient warming did not influence the amount of bacterial sedimentation on either plate position. It is important to remember, that the introduction of an efficient forced-air patient warming system initially led to a major decrease in wound infections, which had a higher incidence in un-



# CONSORT

TRANSPARENT REPORTING of TRIALS

## CONSORT 2010 Flow Diagram

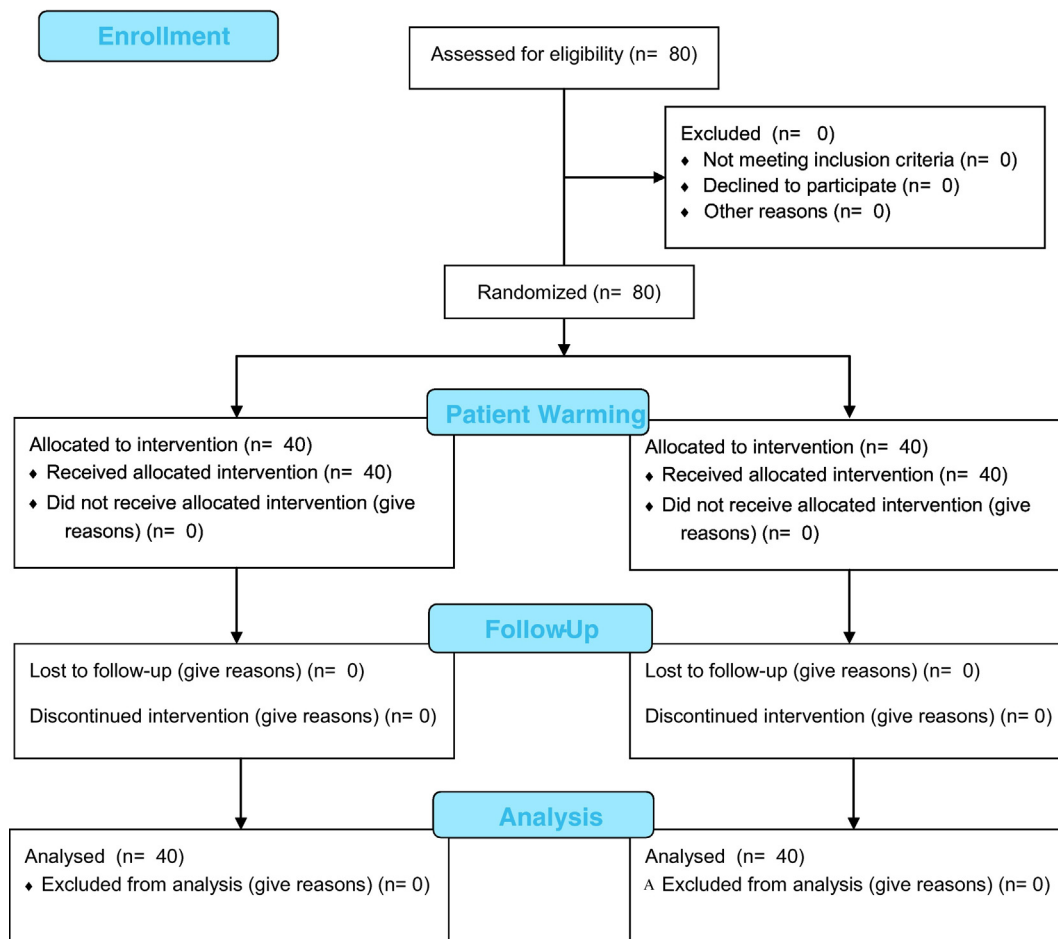


Fig. 1. Consort flow diagram.

warmed patients with accidental perioperative hypothermia [14]. Evidence for the many beneficial effects of perioperative normothermia is undeniably fully established. However, over the last years there has been a lively discussion if the air from forced air warming devices

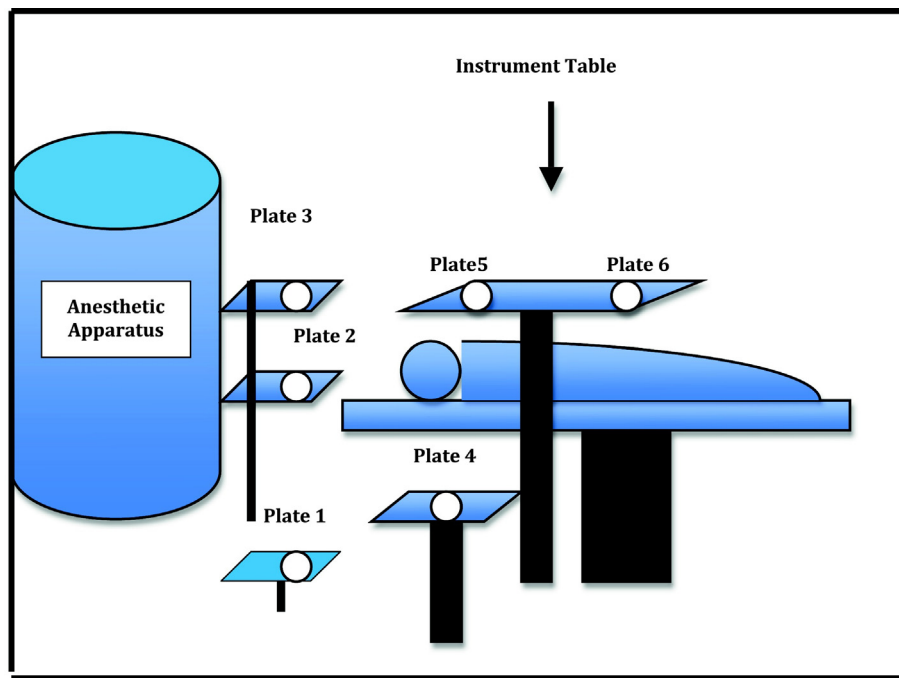
might directly distribute bacteria originating from the environment or the inside of the device into the sterile field in clinically relevant amounts, as micro-organisms have been detected in such warming devices and in the air coming from those devices [15–18].

Table 1

Demographic data, type of surgery, number of health professionals, duration of surgery by patient warming method and use of laminar airflow.

	Forced air (n = 40)		Electric blanket (n = 40)	
	Laminar flow (n = 20)	No laminar flow (n = 20)	Laminar flow (n = 20)	No laminar flow (n = 20)
Age of patients (years)	42 ± 20	48 ± 12	36 ± 8	45 ± 15
Gender of patient (male/female)	10/10	12/8	14/6	7/13
Surgery (%; mean duration in min ± SD; p = 0.13, chi square test)				
Arthroscopy of knee, shoulder and wrist joint (51.48 ± 11.0 min)	55%	35%	70%	55%
Osteosynthesis (47.08 ± 11.96 min)	25%	20%	15%	5%
Metal implant removal (47.50 ± 15.00 min)	0%	20%	5%	5%
Surgery of ligaments and of soft tissue (45.00 ± 13.28 min)	15%	25%	10%	35%
Total knee replacement (60 min)	5%	0%	0%	0%
Number of health professionals	9 (7–12)	7 (5–9)	9 (6–12)	7 (5–9)
Duration of surgery (min)	57 ± 7	40 ± 10	56 ± 7	43 ± 12

Duration of surgery: mean ± SD, number of health professionals: median [range], surgery: frequency (% of all interventions, n = 80).



**Fig. 2.** Positioning of agar plates during the study – plate 1 was positioned 15 cm above floor level, plate 2 at table level, plate 3 at 150 cm, plate 4 at table level with a distance of approximately 50 cm to the sterile operating field. The nitrocellulose membranes (plates 5, 6) were both placed at the sterile instrument table adjacent to each other.

Another focus of this discussion was on the disruption of laminar air-flow by forced air blowers, which was confirmed by some studies [19–22] and rebutted by others [23–26].

In our study it was not possible to detect any higher bacterial counts on any plate in the forced air warming group versus the resistive warming group. The study may obviously not be generalized for an overall safety statement on forced air warming, and is primarily applicable in the particular surgical setup. However – with class action lawsuits “judging” the scientific question of forced air safety with unsuitable, i.e. legal, means subsequent studies are all the more warranted. Only a large, randomized, controlled trial of forced air warming versus non-forced air warming will help to decide, if patient outcome is influenced by the use of forced-air devices. Until this study has been performed, the hypothesized risks of forced air warming remain unclear. With a multitude of factors influencing a patient's risk for perioperative infection, only this kind of study will be able to answer the question, if forced air warming is a major influence on surgical wound contamination, whose voice can be reliably detected in the large choir of all the other factors, such as transmission via the anesthesiologist's [27] or surgeons hand, [28] skin preparation, sterile surgical technique, duration of surgery, surgical skill, patient-related risk factors such as obesity, diabetes mellitus or pre-existing colonization and inadequate antibiotic treatment [29] among many others.

The present study has several limitations. Surgery was primarily minor orthopedic surgery. Unsurprisingly, in the present study no SSIs occurred. However, a study with SSI as endpoint would have required

a much larger setup, since SSIs are rare in the study's particular patient population. The upper-body position of the forced-air warming system in relation to the sterile field on the lower body may have reduced the effect of forced air warming turbulence on airborne contamination in the sterile field. Only the maximum number of health professionals present was recorded in the present study. A more elaborate approach has recently been presented by Masursky et al. [30] However, since the surgeries were not very complex and their duration was relatively short, changes of number of health professionals during surgery was a rare occurrence. Furthermore, the factor “laminar flow” could not be randomized, since OR assignment could not be changed for study purposes. Finally, incidences of opening and closing of doors were not recorded – as the operating theatres are protected by an airlock system, the impact of this factor may not be a major influence.

In conclusion, the present study shows that in the setting of minor orthopedic surgery an OR with laminar airflow, a reduction of surgery time, by trend a reduced number of personnel present, but not the choice of a non-forced air patient warming system was associated with a decreased airborne sedimentation. Optimizing these factors in critical patients with a high risk for the development of SSI may allow further reduction in the incidence of SSIs. As far as forced air warming is concerned subsequent large, randomized controlled patient studies are highly commended to allow evidence based conclusions regarding any influence of forced air warming on perioperative outcome.

**Table 2**

Results of a multivariate analysis of factors influencing bacterial deposition (generalized linear model with gamma distribution and log link, exp (B) and 95% Wald confidence intervals in brackets).

	Plate 1	Plate 2	Plate 3	Plate 4	Plate 5 & 6
Absence of laminar flow	2.42 (1.00–5.83)*	3.70 (2.05–6.67)#	3.48 (1.61–7.51)*	5.10 (2.59–10.06)#	2.18 (1.13–4.20)*
Presence of forced air warming	1.13 (0.74–1.71)	1.07 (0.70–1.65)	1.30 (0.7–2.38)	1.55 (0.92–2.60)	1.00 (0.56–1.80)
Duration (min)	1.05 (1.02–1.07)#	1.03 (1.01–1.05)*	1.05 (1.02–1.07)#	1.05 (1.03–1.07)#	1.02 (1.00–1.05)+
Number of health professionals in OR (5–12)	0.92 (0.72–1.17)	1.05 (0.93–1.20)	1.04 (0.80–1.35)	1.11 (0.90–1.37)	0.86 (0.66–1.11)

+ p = 0.07.

\* p ≤ 0.05.

# p < 0.001.

## Disclosures and funding

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## Conflict of interest

Oliver Kimberger has received financial support for studies and travel costs and fees for speaker assignments from the following companies producing patient temperature management products: Biegler GmbH, Mauerbach, Austria; Augustine Biomedical, Eden Prairie, MN, USA; Möck&Möck, Hamburg, Germany; Zoll, USA; Zoll, San Jose, CA, USA; 3 M, St. Paul, MN, USA; Dräger AG, Lübeck, Germany; 3M, St. Paul, MN, USA; The 37 Company, Amersfoort, the Netherlands.

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# **EXHIBIT DX70**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS

# What Orthopaedic Operating Room Surfaces Are Contaminated With Bioburden? A Study Using the ATP Bioluminescence Assay

Raveesh Daniel Richard MD, Thomas R. Bowen MD

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## Abstract

**Background** Contaminated operating room surfaces can increase the risk of orthopaedic infections, particularly after procedures in which hardware implantation and instrumentation are used. The question arises as to how surgeons can measure surface cleanliness to detect increased levels of bioburden. This study aims to highlight the utility of adenosine triphosphate (ATP) bioluminescence technology as a novel technique in detecting the degree of contamination within the sterile operating room environment.

**Questions/Purposes** What orthopaedic operating room surfaces are contaminated with bioburden?

**Methods** When energy is required for cellular work, ATP breaks down into adenosine diphosphate (ADP) and phosphate (P) and in that process releases energy. This

process is inherent to all living things and can be detected as light emission with the use of bioluminescence assays. On a given day, six different orthopaedic surgery operating rooms (two adult reconstruction, two trauma, two spine) were tested before surgery with an ATP bioluminescence assay kit. All of the cases were considered clean surgery without infection, and this included the previously performed cases in each sampled room. These rooms had been cleaned and prepped for surgery but the patients had not been physically brought into the room. A total of 13 different surfaces were sampled once in each room: the operating room (OR) preparation table (both pre- and postdraping), OR light handles, Bovie machine buttons, supply closet countertops, the inside of the Bair Hugger™ hose, Bair Hugger™ buttons, right side of the OR table headboard, tourniquet machine buttons, the Clark-socket attachment, and patient positioners used for total hip and spine positioning. The relative light units (RLUs) obtained from each sample were recorded and data were compiled and averaged for analysis. These values were compared with previously published ATP benchmark values of 250 to 500 RLUs to define cleanliness in both the hospital and restaurant industries.

**Results** All surfaces had bioburden. The ATP RLUs (mean ± SD) are reported for each surface in ascending order: the OR preparation table (postdraping;  $8.3 \pm 3.4$ ), inside the sterilized pan ( $9.2 \pm 5.5$ ), the inside of the Bair Hugger™ hose ( $212.5 \pm 155.7$ ), supply closet countertops ( $281.7 \pm 236.7$ ), OR light handles ( $647.8 \pm 903.7$ ), the OR preparation table (predrapping;  $1054 \pm 387.5$ ), the Clark-socket attachment ( $1135.7 \pm 705.3$ ), patient positioners used for total hip and spine positioning ( $1201.7 \pm 1144.9$ ), Bovie machine buttons ( $1264.5 \pm 638.8$ ), Bair Hugger™ buttons ( $1340.8 \pm 1064.1$ ), tourniquet machine buttons ( $1666.5 \pm 2144.9$ ), computer keyboard ( $1810.8 \pm 929.6$ ),

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and the right side of the OR table headboard ( $2539 \pm 5635.8$ ).

**Conclusions** ATP bioluminescence is a novel method to measure cleanliness within the orthopaedic OR and can help identify environmental trouble spots that can potentially lead to increased infection rates. Future studies correlating ATP bioluminescence findings with microbiology cultures could add to the clinical utility of this technology.

**Clinical Relevance** Surfaces such as the undersurface of the OR table headboard, Bair Hugger™ buttons, and tourniquet machine buttons should be routinely cleansed as part of an institutional protocol. Although correlation between ATP bioluminescence and clinical infection was not evaluated in this study, it is the subject of future research. Specifically, evaluating microbiology samples taken from these environmental surfaces and correlating them with increased bioburden found with ATP bioluminescence technology can help promote improved surgical cleaning practices.

## Introduction

Healthcare-associated infections often have multiple etiologies, of which cleanliness of hospital surfaces can play a large role [11]. This is perhaps most important in the operating room, where a sterile environment is paramount to decreasing the burden of hospital-acquired morbidity and surgical site infections. Contaminated hospital surfaces greatly contribute to the transmission of healthcare-associated pathogens, including methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant *Enterococcus* spp (VRE), and *Clostridium difficile* [19, 21]. In fact, MRSA and VRE can survive for weeks on environmental surfaces in healthcare facilities [4]. Evidence exists demonstrating that when patients enter a room previously occupied by a patient with MRSA, VRE, *Acinetobacter* spp, or *C. difficile*, the new patient is at increased risk for acquiring the infection [12, 19, 21].

First used in the food industry, adenosine triphosphate (ATP) bioluminescence monitoring has been become broadly applicable in the healthcare setting to provide rapid results regarding hospital cleanliness with improved benefits in the control of surface contamination and application of corrective action against poor hygiene [1, 3]. Because ATP hydrolysis ( $\text{ATP} \rightarrow \text{ADP} + \text{P}_i + \text{energy}$ ) is inherent to all living organisms, including bacteria, ATP bioluminescence monitoring is a convenient method to visualize localized bioburden on contaminated surfaces. Hospitals have developed numerous cleaning protocols to reduce contamination in the clinical setting. For instance, Boyce

et al. measured surface contamination of five high-touch surfaces in patient rooms including bedside rails, overbed tables, television remote controls, toilet seats, and bathroom grab bars [5]. Inadequate cleaning practices were documented by determining aerobic colony counts and by use of an ATP bioluminescence assay [5].

Within orthopaedic surgery, surgical site infection has become an important focus, particularly in total joint arthroplasty. In addition to the Surgical Care Improvement Project (SCIP) guidelines and other recommendations from the American Academy of Orthopaedic Surgeons (AAOS) such as limiting operating room traffic, efforts to reduce the burden of nosocomial orthopaedic infections have become increasingly important. Previous clinical studies and studies in the restaurant industry have established ATP benchmark values of 250 to 500 relative light units (RLUs) to define cleanliness [13, 16]. To our knowledge, no previous study has evaluated the use of ATP bioluminescence as a measurement of cleanliness in orthopaedic surgery operating rooms.

We therefore asked: Utilizing ATP bioluminescence, what orthopaedic operating room surfaces are contaminated with bioburden?

## Patients and Methods

This was a prospective diagnostic study. Because there was no patient contact in our study, institutional review board exemption was obtained, and an ATP bioluminescence assay kit was used to measure the cleanliness of surfaces in orthopaedic operating rooms.

ATP bioluminescence assay kits essentially consist of chemically impregnated reagent swabs and a luminometer. Specifically, a compartmentalized releasing-buffering agent in the swabs lyse the cell walls of microorganisms, rapidly releasing ATP. Only live cells requiring ATP for energy metabolism release ATP in this process. The luminometer contains the firefly enzyme, luciferase, which produces a simple bioluminescence reaction when it encounters the released ATP [14]. The amount of ATP produced is measured in RLUs with standards set by the manufacturer. Measuring the amount of bioluminescence from an ATP reaction provides a valuable indication of surface cleanliness because the quantity of light generated by the enzyme reaction is directly proportional to the amount of ATP present in the sample. Because bacteria and other living microorganisms produce ATP, the measurement of bioluminescence is indicative of contamination in a sterile environment [13].

After an orthopaedic surgery had been performed, the six operating rooms were cleaned as per routine hospital protocol in preparation for the next case (two adult reconstruction, two trauma, two spine). A cloth composed

of 80% rayon, 15% polypropylene, and 5% polyester was dampened with hydrated ethyl alcohol at 70% (w/v) and then swept over a surface for at least 10 seconds. Before patient entry into the room, ATP bioluminescence swabs (3 M™ Clean-Trace™ Surface ATP UXL100; 3 M Corporation, St Paul, MN, USA) were used to take samples of areas in the operating room that were on a spectrum of dirty to sterile after terminal cleaning. “Dirty” surfaces were those considered to be inadequately cleaned between cases as a result of either inattention by environmental service staff (ie, Bair Hugger™ buttons/hose [3 M Corp.]), surfaces without direct contact with patients (ie, operating room [OR] shelves), or surfaces that routinely were used by OR personnel that were not scrubbed into the procedure (ie, computer keyboards).

The swabs were then analyzed with the use of the handheld luminometer (3 M™ Clean-Trace™ NG Luminometer Version 3.0 [NGi]) that measured the amount of bioburden for the given area that was swabbed. The amount of ATP, both microbial and nonmicrobial, was quantified and expressed as RLUs. This number was recorded and compared with thresholds for contamination set by the hospital industry standard of > 500 RLUs [7, 13, 16]. In addition, we utilized published acceptability limits for kitchen surfaces used in the restaurant industry of < 400 RLUs, published by Osimani et al [15]. In this study, sampled surfaces that were above the restaurant industry standard of 400 RLUs and certainly over previously published hospital standards of 500 RLUs were considered contaminated in the sterile OR environment. As previously published, the ATP bioluminescence linearly represents the degree of bioburden and is repeatable in its readings,

although some spread/scatter in RLU measurements is expected [14].

Two control points were chosen based on the assumption of bioburden that these surfaces typically carry. The “sterile” control was the inside of a sterilized pan, whereas the “dirty” control was the keyboard of one of the OR computers. Additionally, 11 different surfaces with high-volume contact were tested for ATP bioluminescence: the OR preparation table (both pre- and postdraping), OR light handles, Bovie machine buttons, supply closet countertops, the inside of the Bair Hugger™ hose, Bair Hugger™ buttons, right side of the OR table headboard, tourniquet machine buttons, the Clark-socket attachment, and patient positioners used for total hip and spine positioning. These 13 points of interest were tested in a total of six orthopaedic operating rooms for a total of 78 data points.

## Results

All surfaces had bioburden (Table 1; Fig. 1). The ATPRLUs (mean  $\pm$  SD) are reported for each surface in ascending order: the OR preparation table (postdraping;  $8.3 \pm 3.4$ ), inside the sterilized pan ( $9.2 \pm 5.5$ ), the inside of the Bair Hugger™ hose ( $212.5 \pm 155.7$ ), supply closet countertops ( $281.7 \pm 236.7$ ), OR light handles ( $647.8 \pm 903.7$ ), the OR preparation table (predrapping;  $1054 \pm 387.5$ ), the Clark-socket attachment ( $1135.7 \pm 705.3$ ), patient positioners used for total hip and spine positioning ( $1201.7 \pm 1144.9$ ), Bovie machine buttons ( $1264.5 \pm 638.8$ ), Bair Hugger™ buttons ( $1340.8 \pm 1064.1$ ), tourniquet machine buttons ( $1666.5 \pm 2144.9$ ), computer keyboard ( $1810.8 \pm 929.6$ ),

**Table 1.** Degree of bioburden on orthopaedic operating room surfaces measured in relative light units (RLUs)

OR surface	Mean	SD	Minimum	Maximum
Inside sterilized pan	9.2	5.5	5	20
OR preparation table (predrape)	1054	387.5	403	1562
OR preparation table (postdrape)	8.3	3.4	5	14
OR light handles	647.8	903.7	84	2456
Bovie machine buttons	1264.5	638.8	366	2278
Supply closet countertops	281.7	236.7	83	677
Inside Bair Hugger™ hose	212.5	155.7	72	423
Bair Hugger™ buttons	1340.8	1064.1	278	2880
Right side of OR table headboard	2539	5635.8	142	14,042
Tourniquet machine buttons	1666.5	2144.9	453	5994
Clark-socket attachment	1135.7	705.3	273	2159
Patient positioner	1201.7	1144.9	296	3428
Computer keyboard	1810.8	929.6	297	2588

OR = operating room.

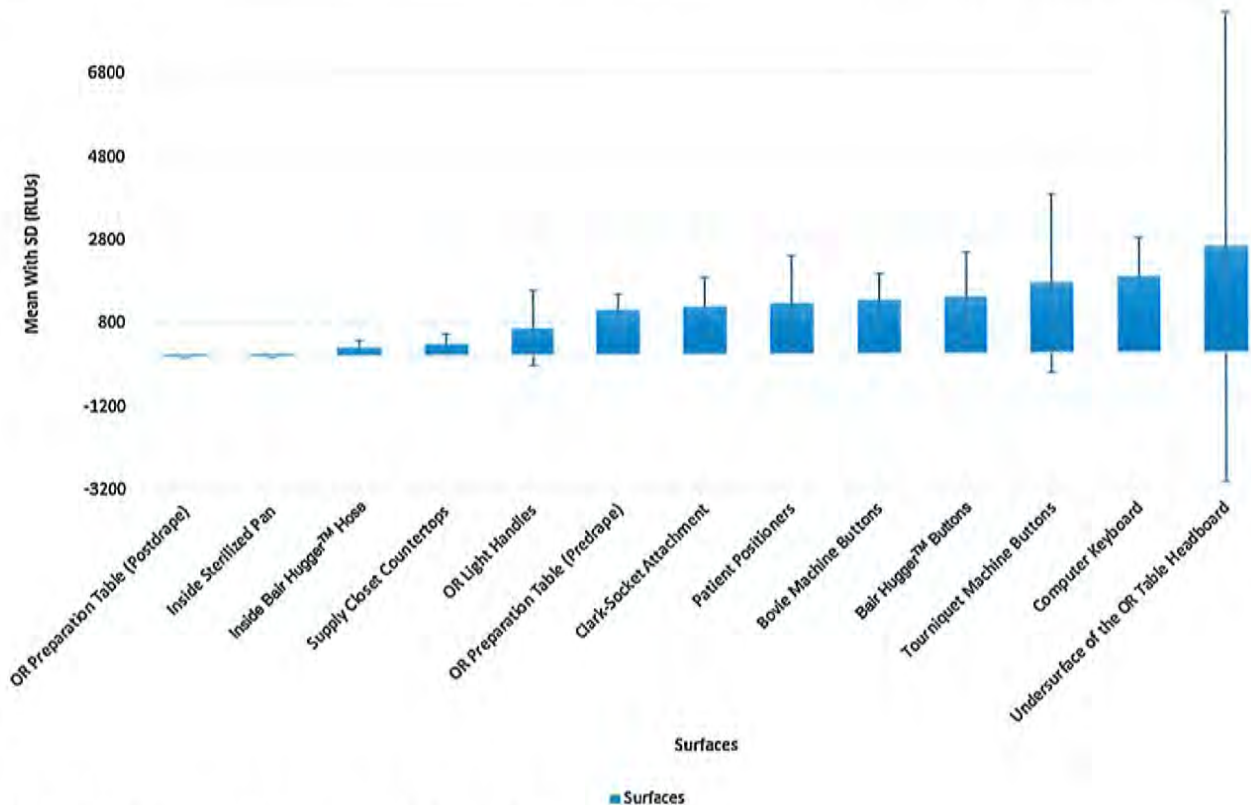


Fig. 1 Degree of bioburden on orthopaedic OR surfaces as measured in RLUs.

and the right side of the OR table headboard ( $2539 \pm 5635.8$ ). Overall, the surface with the cleanest surface was the OR preparation table postdraping (average 8 RLUs) with the dirtiest surface being the right side of the OR table headboard (average 2539 RLUs).

## Discussion

Contaminated OR surfaces can increase the risk of orthopaedic infections, particularly after procedures in which hardware implantation and instrumentation are used. The question then arises as to how surgeons can measure surface cleanliness to detect increased levels of bioburden. This study aims to highlight the utility of ATP bioluminescence technology as a useful technique in detecting the degree of contamination within the sterile OR environment. Our results demonstrate that several surfaces that are considered “clean” within the OR are in fact not as clean as one may think. Surfaces such as the undersurface of the OR table headboard and machine buttons should be routinely cleaned as a part of the routine OR cleaning protocol to reduce the amount of OR bioburden.

Limitations of ATP bioluminescence testing do exist. It must be stated that increased RLU measurements do not

directly correlate to increased clinical infection rates. Still, some authors have demonstrated evidence that when patients enter a room previously occupied by a patient with MRSA, VRE, *Acinetobacter* spp, or *C. difficile*, and where environmental surfaces have not been thoroughly cleaned, the new patient is at increased risk for acquiring the infection [12, 19]. This concept can be applied to the OR. Theoretically, there is an increased risk of nosocomial infection in OR environments that have not been adequately decontaminated in between cases, further highlighting the utility of this present study. Additionally, it has been proposed that organic debris can account for approximately 66% of ATP on surfaces [10]. Thus, ATP assays can be oversensitive and can potentially overestimate the degree of bacterial bioburden on surfaces. Some studies have highlighted a lack of a true correlation between ATP readings and aerobic colony counts, noting that additional environmental factors such as residual detergent/disinfectants, poor surface conditions, and ammonium cleaning compounds can highly increase or decrease ATP readings [6, 7, 10, 15, 17]. Conversely, false-negative ATP bioluminescence results have been reported in surfaces cleaned with bleach-based disinfectants [9, 18, 20]. Perhaps the biggest limitation to ATP bioluminescence assay kits is the poor detection of Gram-

negative bacteria. An animal study by Turner et al. demonstrated that ATP bioluminescence detection of Gram-negative bacteria improved with sonication, suggesting that the buffer in the assay incompletely lyses the cell walls of Gram-negative bacteria [18, 20]. Sonication, however, did not improve the detection of *S aureus*, indicating that the chemical reagents readily lyse the cell walls of Gram-positive bacteria.

Routine visual inspection has repeatedly been shown to underestimate the degree of bioburden in the healthcare setting [8, 13, 16]. The measurement of organic ATP on surfaces using a luciferase assay and luminometer has been used in the food preparation industry for more than 30 years [11]. Although sensitivity varies between commercially available systems, ATP benchmark values of 250 to 500 RLUs have been used to define cleanliness with very low readings typically associated with low aerobic colony counts [13, 16]. Conversely, very high RLU readings can represent viable bioburden, organic debris, or a combination of both [7]. Using a benchmark of 100 RLUs, Anderson et al. found that 84% (37 of 44) items in a surgical ward exceeded this standard and were considered contaminated [2]. Similarly, other studies have raised concerns regarding the standards of surface cleanliness in the hospital environment [8, 16, 19]. If we are to compare our study results with the criteria set forth by the restaurant industry, as outlined previously, the only surfaces in our ORs that would be considered "clean" are the OR preparation table (postdraping), the inside of a sterilized pan, the inside of the Bair Hugger<sup>TM</sup> hose, and the supply closet countertops. This is frankly alarming. Surfaces such as OR light handles, the Clark-socket attachment, patient positioners used for total hip and spine positioning, and the right side of the OR table headboard, to name a few, would not even pass restaurant standards so why should this be considered appropriate for the sterile OR environment? It is this precise question that our study aims to highlight. The near  $\times 100$  variance of RLU measurements in this study can be explained by the lack of routine cleaning of the surfaces with the highest RLU measurements. This was reproducible throughout the six ORs tested and implies that better cleaning practices need to be instituted to address this oversight. Per Sherlock et al. [18], an amendment in cleaning practice at their institution led to a decrease in ATP bioburden in a hospital setting (average of 612 RLUs precleaning versus 375 RLUs postcleaning).

Despite cleaning, we found bioburden levels that would be concerning even in the food industry [13, 16] on OR light handles, the OR preparation table (predrapping), the Clark-socket attachment, patient positioners used for total hip and spine positioning, Bovie machine buttons, Bair Hugger<sup>TM</sup> buttons, tourniquet machine buttons, computer keyboards, and the right side undersurface of the OR

table headboard. Although not all these surfaces may physically make contact with the patient, the presence of contamination within a sterile OR environment could potentially lead to further contamination. It is conceivable that the surgeon, nurse, or anesthesiologist could transfer bacteria from one surface to another or to the patient simply by touching the Bair Hugger<sup>TM</sup> buttons, tourniquet machine, or light handles and not washing their hands directly afterward. This suggests that more attention needs to be paid to those surfaces during the terminal cleaning and sterilization processes between surgical procedures. Griffith et al. [10] demonstrated that 61% of surfaces within the OR environment were considered unacceptable in cleanliness. Utilizing established ATP benchmarks of 500 RLUs and microbiology surface samples with less than 2.5 colony forming units (CFUs)/cm<sup>2</sup>, the authors demonstrated that visual inspection alone would grossly underestimate the level of cleanliness in the OR suite. Although a direct correlate between these established benchmarks and clinical infection has not been shown, it is conceivable that contamination above these thresholds could potentially increase the risk of surgical site infection. This issue seems especially important in orthopaedic surgery, where hardware implantation is commonplace and any increased potential for bioburden would seem to result in a serious concern about infection. Our results demonstrate that multiple surfaces in the OR were contaminated. It is conceivable that when OR personnel clean in between cases, these surfaces are often left untouched and do not get wiped down because they do not routinely have direct contact with patients or within the surgical field. However, it must be noted that, at our institution, the right side of the OR table headboard is often an area that is used for placing the suction tip used by anesthesia to clear secretions during induction/intubation and postextubation. Considering the bioburden in oral flora, this is a critical part of the OR that often goes uncleaned and can potentially contribute to increased surgical site infections [4, 12, 19].

It is assuring that surfaces expected to be clean such as the prepped OR table and sterilized pans were indeed near negligible with bioburden. It was somewhat surprising that although the inside of the Bair Hugger<sup>TM</sup> hose does not routinely get cleaned at our institution, the degree of bioburden was relatively small compared with other OR surfaces. Perhaps this finding can be attributed to limited exposure to the environment, especially because surfaces that were routinely touched by hand (computer keyboards, tourniquet machine buttons, Bair Hugger<sup>TM</sup> buttons, patient positioners, and Clark-socket attachments) had the highest overall RLUs on bioluminescence testing.

ATP bioluminescence is a novel method to measure cleanliness within the orthopaedic OR and can help identify environmental trouble spots that can potentially lead to

increased infection rates. Surfaces such as the undersurface of the OR table headboard, Bair Hugger™ buttons, and tourniquet machine buttons should be routinely cleansed as part of an institutional protocol. Although a direct correlation between ATP bioluminescence and clinical infection was not evaluated in this study, it is the subject of future research. Specifically, evaluating microbiology samples taken from these environmental surfaces and correlating them with increased bioburden found with ATP bioluminescence technology can help promote improved surgical cleaning practices. Improved cleanliness of hospital surfaces can help reduce risk of nosocomial infections, particularly related to surgery [4, 12, 16, 19]. Although our results are in some ways encouraging, they also reveal that many surfaces in a supposedly “sterile” environment often go uncleaned. Within orthopaedic surgery, where routine implantation of metallic prostheses and hardware predominates, reducing the risk of environmental contamination is imperative.

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# **EXHIBIT DX71**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In Re: Bair Hugger Forced )  
Air Warming Products )  
Liability Litigation: )  
)  
) MDL No.: 15-2666  
) (JNE/FLN)  
This Document Relates To: )  
)  
All Actions. )  
\_\_\_\_\_)

VIDEOTAPED DEPOSITION OF WILLIAM R. JARVIS, M.D.  
San Francisco, California  
Tuesday, July 25, 2017

BY: HEIDI BELTON, CSR, RPR, CRR, CCRR, CLR  
CSR LICENSE NO. 12885  
JOB NO. 124789

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1 MR. C. GORDON: I think it was this one.  
 2 MR. B. GORDON: Okay.  
 3 BY MR. C. GORDON:  
 4 Q. Have you made it to page 46 yet?  
 5 A. Yes.  
 6 Q. And there's a -- this is a -- essentially  
 7 minutes of a presentation given by Dr. Michael Bell,  
 8 the deputy director for the Division of Healthcare  
 9 Quality Promotion, of the CDC; right?  
 10 A. Correct.  
 11 Q. Do you know Dr. Bell?  
 12 A. I do.  
 13 Q. In fact, it's Dr. Bell you've quoted in  
 14 your report that -- words to the effect of nothing  
 15 that blows air should be in an operating room;  
 16 right?  
 17 A. Correct.  
 18 Q. And by -- you understood Dr. Bell to be  
 19 referring to any piece of equipment that blows air.  
 20 Is that -- that was your understanding?  
 21 A. Correct.  
 22 Q. So that would include computers that have  
 23 little fans with CPUs in them; right?  
 24 A. Well, he didn't give an exhaustive list of  
 25 what he meant.

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1 oversight?  
 2 A. I wouldn't agree with that.  
 3 Q. Okay. So is it a -- as far as you know,  
 4 is there a process within the CDC whereby for  
 5 something to become an official position of the CDC  
 6 there's some process that has to be undertaken?  
 7 A. I'd say there's numerous processes. For  
 8 instance, if you look at -- in a CDC publication,  
 9 there's a very specific process that you go through  
 10 to get clearance of a paper that you publish at CDC.  
 11 And yet at the bottom of the paper there's usually a  
 12 disclaimer that it doesn't repre- -- necessarily  
 13 represent the views of CDC.  
 14 Q. Okay. Is it your understanding as you sit  
 15 here today that it's the official position of the  
 16 Centers for Disease Control that no equipment that  
 17 blows air should be in an operating room?  
 18 A. Well, again, I can't speak for CDC. So  
 19 I'd be speculating. Certainly Dr. Michael Bell has  
 20 said that. And I presume Dr. Denise Cardo, that's  
 21 his boss who would have reviewed this, agrees with  
 22 that. I can't tell you how far up the chain of  
 23 command it would have gone.  
 24 Q. Well, let's see what Dr. Bell says in  
 25 Exhibit 24, which you have in front of you.

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1 Q. Did he give any list?  
 2 A. Well, he was talking about heater-cooler  
 3 units. But he didn't -- no, he did not give an  
 4 exhaustive list.  
 5 Q. Dr. Bell doesn't speak for the CDC; does  
 6 he?  
 7 A. I don't know how you define that. He's  
 8 deputy director of the division. So when he's  
 9 speaking at a meeting like this, he certainly is  
 10 speaking for CDC.  
 11 Q. Okay. So if he says this is the way it  
 12 is, that is a pronouncement -- an official  
 13 pronouncement of the Centers for Disease Control; is  
 14 that what you're saying?  
 15 MR. B. GORDON: Objection to form.  
 16 Argumentative.  
 17 THE WITNESS: Well, I guess that you would  
 18 have to ask the director of CDC that question  
 19 because it probably varies by the director and who's  
 20 saying it and what they're saying.  
 21 BY MR. C. GORDON:  
 22 Q. Well, in your experience does -- somebody  
 23 who is a deputy director of a division, do they have  
 24 the authority to speak as -- for the CDC? Without  
 25 any vetting, without any review, without any

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1 Do you see where Dr. Bell at the very  
 2 bottom of page 46 says that -- it says that Dr. Bell  
 3 shared this draft device selection algorithm with  
 4 HICPAC --  
 5 A. Yes.  
 6 Q. -- do you see that?  
 7 Okay. And then on the next page there's a  
 8 device selection algorithm. Don't worry. I'm not  
 9 going to try and make you read that.  
 10 A. Thank you.  
 11 Q. But do you have any idea, first of all,  
 12 what -- what the word "draft" means in this context?  
 13 A. I'm assuming that it means that he's put  
 14 this together and he's sharing it with HICPAC to get  
 15 their comments and suggestions and it's not final  
 16 yet.  
 17 Q. That would be a normal process; wouldn't  
 18 it?  
 19 A. Well, it is a process, yes.  
 20 Q. And the statement that you've quoted about  
 21 "nothing that blows air should be in an operating  
 22 room," that pre-dated this; didn't it?  
 23 A. Yes.  
 24 Q. And it was in the context of a HICPAC  
 25 discussion about how to deal with the heater-cooler

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1 situation; right?

2 A. And Dr. Bell's assessment of other  
3 equipment that has blowing air in the operating  
4 room. I don't think he was being specific only to  
5 heater-coolers or he would have said no  
6 heater/cooler device should be in an operating room.

7 (Exhibit 25 marked.)

8 BY MR. C. GORDON:

9 Q. Okay. Well, I'm going to give -- show you  
10 Exhibit 25. And I will represent to you that this  
11 is a readable version of the device selection  
12 algorithm that appears on page 47. And if you  
13 follow that algorithm through, the algorithm starts  
14 with a product X. And first question is, is it  
15 reusable, yes or no.

16 Bair Huggers are reusable; right?

17 A. Correct.

18 Q. So you go over to the yes side. And then  
19 is it used in a patient care area? High risk,  
20 non-risk, or no-patient exposure.

21 We'll put the Bair Hugger in a high-risk  
22 area; right?

23 A. I would.

24 Q. Okay. Then the next line down to the left  
25 is "Is there" -- the box is "air/water interface."

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1 Do you see that?

2 A. Yes.

3 Q. Okay. And by the way, if you -- the text  
4 on page 47 specifically says the high-risk box  
5 includes consideration of the air/water interface  
6 through processing issues," et cetera, et cetera.

7 Now, under "air/water interfaced" -- under  
8 "air/water interface," the second box over from the  
9 left is "uses fan"; right?

10 A. Correct.

11 Q. But under this algorithm you don't get to  
12 whether it uses a fan or not unless there's an  
13 air/water interface; correct?

14 MR. B. GORDON: Objection to counsel's  
15 characterization of the document and his testimony  
16 about what this means.

17 Also refer you to this paragraph for a  
18 moment.

19 THE WITNESS: I'm sorry?

20 MR. B. GORDON: That's what he referred  
21 you to there, the bottom of there.

22 THE WITNESS: Is there a question?

23 MR. C. GORDON: Yup.

24 Could you read it back, please.

25 (Record read as follows:

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1 "Q. But under this algorithm you don't  
2 get to whether it uses a fan or not  
3 unless there's an air/water interface;  
4 correct?")

5 THE WITNESS: It actually looks like when  
6 they're discussing it, that in fact that air/water  
7 interface is merely being reinterpreted more as air  
8 or water and not necessarily air/water interface.  
9 And there's a considerable amount of discussion by  
10 HICPAC members about adding a section regarding  
11 whether a device can be cleaned at all, which we  
12 know 3M has no recommendation for cleaning the hoses  
13 of the device.

14 BY MR. C. GORDON:

15 Q. Can you show me where there's this  
16 discussion where you contend it means -- shows that  
17 the air/water interface means air or water?

18 MR. B. GORDON: I'm going to object. He  
19 was in the middle of a sentence in explaining  
20 exactly that. So let him finish.

21 MR. C. GORDON: I want to -- he can come  
22 back and give a speech. I want to focus on the  
23 air/water interface issue, not the cleaning issue.

24 MR. B. GORDON: He's answering the  
25 question to the best of his ability in the context

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1 of this document and what you showed him.

2 BY MR. C. GORDON:

3 Q. Where in --

4 MR. B. GORDON: You interpreted it one  
5 way. He's trying to give you his interpretation.

6 BY MR. C. GORDON:

7 Q. Right. Where in this document does it say  
8 that air/water interface really means air or water?

9 MR. B. GORDON: I object to interrupting  
10 the witness. Please let him finish his answer.

11 THE WITNESS: On page 47 at the bottom it  
12 says, "High-risk box includes consideration of  
13 air/water interface reprocessing issues and  
14 instructions. Under the air/water interface are  
15 items related to moisture, creates mist, uses fan,  
16 requires water, uses tubing, dry-ability, biofilm,  
17 resistance. These elements were included to  
18 stimulate thinking. First-cut elements were  
19 included to stimulate thinking about items that  
20 impact reprocessing, as well as" -- blah, blah,  
21 blah, blah, blah, blah, blah. And then they go on  
22 to talk about the importance of cleaning devices.  
23 "And the manufacturer should be providing better  
24 instructions for cleaning devices."

25 BY MR. C. GORDON:

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1 Q. Is there --

2 A. It says, "Inclusion of air/water is  
3 laudable. Air and water should receive attention  
4 particularly after the experience with heater-cooler  
5 units when their emissions were not taken into  
6 account." That's page 48, fourth from the bottom  
7 paragraph.

8 They also talk about maintenance is  
9 important. Should be part of the criteria, which we  
10 know. The hoses in the Bair Hugger cannot be  
11 cleaned. There's no recommendation for that at all.  
12 It says, "Consideration should be given to the  
13 composition of the materials in the device such as  
14 tubing links." We know that can be a problem.

15 Q. Doctor, I'll let you come back and talk  
16 about cleaning all you want because I know that's  
17 the big -- that you want to. But is there anything  
18 else in here that talks about the air/water  
19 interface? And I want to specifically focus on your  
20 testimony from a few moments ago where you said you  
21 read something that said it's air or water.

22 MR. B. GORDON: Object to the form. And  
23 counsel's mischaracterizing his testimony; it's  
24 argumentative. It says "air/water." You interpret  
25 that one way. He's explained his interpretation.

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1 THE WITNESS: And they talk about --  
2 Dr. Bell says, "The algorithm is a collection of  
3 elements to be considered. Weighing a different  
4 element needing to be taken into consideration is  
5 likely to be challenging."

6 BY MR. C. GORDON:

7 Q. Is there anything in here that says that  
8 when it says air/water interface what that really  
9 means is air or water?

10 MR. B. GORDON: Object to the form.  
11 Argumentative. It doesn't say "air and water." It  
12 says "air/water."

13 THE WITNESS: (Witness reviews document.)

14 MR. B. GORDON: And it's asked and  
15 answered. He's referred you to that sentence on  
16 page 48.

17 THE WITNESS: Yeah, I would just say my  
18 last answer is what I would say. If you look at  
19 it -- he's asking for additional comments and  
20 suggestions. And my interpretation of that is  
21 air/water was could be air or water.

22 BY MR. C. GORDON:

23 Q. So you believe when they -- it says air  
24 and water should receive attention," that really  
25 means air or water?

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1 MR. B. GORDON: Object to form.  
2 Argumentative.

3 THE WITNESS: Well, I think it means it  
4 could be air and water or and/or water. And they're  
5 talking about devices that need to be cleaned and  
6 they're talking about devices that have hoses.

7 BY MR. C. GORDON:

8 Q. What does the word "interface" mean to  
9 you?

10 A. Where two things interface.

11 Q. You have to have two things; right --

12 A. Right.

13 Q. -- not just one?

14 MR. B. GORDON: Objection to form.

15 THE WITNESS: It could be. That could be  
16 one interpretation. Again this is a draft. And  
17 he's asking for comments from other people in the  
18 room.

19 BY MR. C. GORDON:

20 Q. What would an air interface be?

21 A. For instance, where the hose from the Bair  
22 Hugger comes in contact with the blanket would be an  
23 interface. And we know they're talking about  
24 connections with hoses.

25 Q. I know. I'm talking about where it says

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1 "air/water interface." You're saying that your  
2 interpretation of that is it means air or water  
3 interface. I'm asking what's an air interface?

4 MR. B. GORDON: Objection to form.  
5 Argumentative. Asked and answered.

6 THE WITNESS: Well, I -- and I just  
7 described one for you.

8 BY MR. C. GORDON:

9 Q. And you think that's what Dr. Bell is  
10 talking about and the HICPAC people are talking  
11 about, that it's any -- any air interface with  
12 anything I said?

13 MR. B. GORDON: Objection to form.  
14 Characterization of the record. And argumentative.

15 THE WITNESS: Well, they're talking about  
16 medical devices that are in the operating room.

17 THE REPORTER: They're talking about what?

18 THE WITNESS: Medical devices that are in  
19 the operating room.

20 BY MR. C. GORDON:

21 Q. Actually, Doctor, they're talking about  
22 devices where there's water and an interface with an  
23 -- with the air in such a way that the bacteria that  
24 could grow in the water could be aerosolized into  
25 the air --

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1 MR. B. GORDON: Objection. Counsel's  
2 testifying.

3 BY MR. C. GORDON:

4 Q. -- isn't it?

5 A. Well, that's one interpretation. That's  
6 yours. I don't see where Dr. Bell specifically says  
7 that, number one. And, number two, if it follows up  
8 on his previous statement that no device blowing air  
9 should be in the operating room, then obviously if  
10 he limits it only to air/water interface, then he's  
11 going to miss out on other potential dangerous  
12 devices.

13 Also, if you think about it, he's  
14 developed this or started the development of this  
15 and hopefully it will lead to further discussion  
16 because of the follow-up investigations that led to  
17 the discovery of heater/cooler units being a  
18 problem.

19 Obviously before that hadn't come up with  
20 this. So hopefully this will be expanded to address  
21 all of those other devices in the operating room  
22 that have exhaust.

23 Q. How much do you charge per hour for your  
24 expert work?

25 A. It varies depending on what I'm doing.

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1 Q. Do you charge those -- all those entities  
2 the same thing?

3 A. Some more; some less.

4 Q. And what's your highest rate for  
5 consulting?

6 A. For a one-hour presentation, it's -- I  
7 think the highest I've charged is \$5,000 or \$7,500.

8 Q. Okay. And if you're doing some sort of  
9 ongoing work as opposed to a single presentation, do  
10 you go by the hour or by the project? Or how do you  
11 do that?

12 A. It varies. I've done both.

13 Q. Do you have a standard hourly rate when  
14 you're billing by the hour?

15 A. It's somewhat dependent upon what I'm  
16 doing.

17 Q. Give me the parameters, ranges.

18 A. If I'm having to deal with media, it's  
19 usually in the 8- or \$900 an hour range. If I'm  
20 doing on-site outbreak investigation, it could be  
21 somewhere in the 500 to \$700 an hour range.

22 Q. When was the last outbreak investigation  
23 you did in the United States?

24 A. Well, I get asked to do them not  
25 infrequently but I don't do them very often for the

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1 Q. Tell me the different rates.

2 A. For review and materials, it's \$700 an  
3 hour. For sitting here with you it's \$800 an hour.  
4 And at trial it's \$900 an hour.

5 Q. Is there a minimum fee for a deposition  
6 too?

7 A. Yes.

8 Q. What's that?

9 A. I got to look. I think it's four or five  
10 hours.

11 Q. And what percentage of your income in the  
12 last couple of years has come from your work as an  
13 expert witness in lawsuits?

14 A. I'd say probably 10, 15 percent.

15 Q. And what's the other 80 or 90 percent come  
16 from?

17 A. My other consulting work that I do.

18 Q. Well, what kind of consulting work do you  
19 do?

20 A. I consult in epidemiology, infectious  
21 disease, hospital epidemiology and infection control  
22 for medical device companies, for infection control  
23 organizations, for ministries of health, for  
24 hospitals or hospital systems, and occasionally for  
25 individual practicing clinicians.

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1 very reason you're talking about. They're very  
2 expensive.

3 Q. Who -- what type of organization asks you  
4 in the United States?

5 A. Hospitals.

6 Q. Is there any reason those hospitals  
7 couldn't go to the CDC and ask them to do  
8 investigation?

9 A. Well, they could go to CDC. But, realize,  
10 CDC is a -- first of all, it's a non-regulatory  
11 agency except for NIOSH. Second is in order to have  
12 CDC come and do an investigation takes a fair number  
13 of approvals. It has to be approved at the branch  
14 level. Then the division level. Then the center  
15 level. And then the -- actually the group that  
16 funds the people that go out and do the outbreak  
17 have to approve it. It has to be approved by the  
18 state health department.

19 So if there was an outbreak at  
20 San Francisco General and they called CDC and said,  
21 "We want you to come do an outbreak investigation."  
22 If the San Francisco Health Department and the  
23 California Health Department didn't concur with  
24 that, they would not be allowed to go do it.

25 And in addition to all that bureaucracy,

# **EXHIBIT DX72**

TO DECLARATION OF PETER J. GOSS IN  
SUPPORT OF DEFENDANTS' MOTION TO  
EXCLUDE PLAINTIFFS' ENGINEERING  
EXPERTS

Confidential - Subject to Protective Order

Page 1

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In Re:

Bair Hugger Forced Air Warming  
Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

DEPOSITION OF RICHARD P. WENZEL, M.D., MSc.

VOLUME I, PAGES 1 - 370

AUGUST 4, 2017

(The following is the deposition of RICHARD  
P. WENZEL, M.D., MSc., taken pursuant to Notice of  
Taking Deposition, via videotape, at the Hausfeld law  
firm, 1700 K Street Northwest, Suite 650, in the City  
of Washington, District of Columbia, commencing at  
approximately 9:08 o'clock a.m., August 4, 2017.)

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1 going on we might only see 30 percent instead of 67  
 2 percent reduction. That's what I recall, and that's  
 3 what I cited in my report.  
 4 Q. But you also cited Scott --  
 5 A. Yeah.  
 6 Q. -- that showed that patients that were SCIP  
 7 non-compliant had a lower infection rate than patients  
 8 that were SCIP compliant.  
 9 A. Well if you look at all infections, that was  
 10 statistically significant, all -- all infections. The  
 11 surgical site he couldn't show a difference.  
 12 Q. Okay. We're not looking at all infections  
 13 here, doctor.  
 14 A. Yeah, okay.  
 15 Q. We're looking at surgical-site infections.  
 16 A. Perfect.  
 17 Q. Which is a wound infection; correct?  
 18 A. Yes.  
 19 Q. Okay. And in the Scott study SCIP  
 20 non-compliant had a lower infection rate than SCIP  
 21 compliant; correct?  
 22 A. You mean a non -- nonsignificant --  
 23 Q. It's nonsignificant, but it was still -- it  
 24 was still lower.  
 25 A. Fine.

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1 Q. Okay. I mean, you're right, it is  
 2 nonsignificant --  
 3 A. Yeah.  
 4 Q. -- because the p value's .7811.  
 5 A. Yeah. Not at all.  
 6 Q. The p value's very high.  
 7 A. Yeah.  
 8 Q. So that would indicate to a scientist, such  
 9 as yourself, that there's no difference between --  
 10 between warming and non-warming.  
 11 A. True.  
 12 Q. Okay.  
 13 MR. COREY GORDON: Object to the form of  
 14 the question.  
 15 Q. Now you spent a considerable amount of time  
 16 going over comorbidities.  
 17 A. Yeah.  
 18 Q. Okay. Can we just agree that the  
 19 comorbidities will be case specific depending on the  
 20 patient?  
 21 MR. COREY GORDON: Object to the form of  
 22 the question.  
 23 A. So if you're asking can I predict the  
 24 infection rate above or below the average as a result  
 25 of incorporating comorbidities, yes. Is that what

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1 you're asking?  
 2 Q. I mean, for example, you talk about diabetes  
 3 and obesity, --  
 4 A. Yeah.  
 5 Q. -- other things.  
 6 But you would agree with me that that  
 7 discussion might be more appropriate when we actually  
 8 know what patient we're talking about; correct?  
 9 MR. COREY GORDON: Object to the form of  
 10 the question.  
 11 MR. ASSAAD: Basis?  
 12 MR. COREY GORDON: Appropriate to what?  
 13 Appropriate to his discussion of why McGovern is not  
 14 effective? No. The word "appropriate" is -- is  
 15 completely vague and meaningless.  
 16 MR. ASSAAD: Why are you yelling to me,  
 17 Corey?  
 18 MR. COREY GORDON: I'm not yelling. I'm --  
 19 You're detecting an exasperated tone in my voice, but  
 20 I'm not yelling.  
 21 MR. ASSAAD: Are you picking up that stick  
 22 to hit me?  
 23 MR. COREY GORDON: Not yet.  
 24 (Laughter.)  
 25 MR. GOSS: Let me tell you, it hurts when

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1 that thing comes down.  
 2 (Laughter.)  
 3 BY MR. ASSAAD:  
 4 Q. Are you aware of articles that discuss that  
 5 the incidence of periprosthetic joint infections are  
 6 going to increase over the next twenty -- up to 2030?  
 7 MR. COREY GORDON: Object to the form of  
 8 the question.  
 9 A. Yeah, related to the increased number of  
 10 people who are undergoing the procedures, so.  
 11 Q. When we talk about incidence, I'm talking  
 12 about the percentage.  
 13 A. Percent?  
 14 Q. Do you recall an article that indicated by  
 15 2030 the -- the incidence of periprosthetic joint  
 16 infections will be as high as 6 percent?  
 17 A. I'm not aware of that at all.  
 18 Q. You would agree with me that being diabetic  
 19 is not a cause of the infection.  
 20 MR. COREY GORDON: Object to the form of  
 21 the question.  
 22 A. I don't agree with that at all. My view of  
 23 infections, surgical-site infections is that they're  
 24 multifactorial and the comorbidities, for example, are  
 25 a -- one factor that can certainly change the baseline

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1 actually pull them out of you; correct?  
 2 A. Well I gave --  
 3 MR. COREY GORDON: Object to the form of  
 4 the question.  
 5 Q. Right?  
 6 A. I was trying -- I mean I was trying to get  
 7 your answer to, you know, is there any difference  
 8 between the two devices.  
 9 Q. And we haven't seen -- we haven't looked at  
 10 the --  
 11 This is just the poster presentation;  
 12 correct?  
 13 A. Yeah.  
 14 Q. Have you seen the manuscript?  
 15 A. I think I've seen the manuscript, I'm trying  
 16 to remember, or at least a draft of something. It  
 17 might be just an enlarged poster.  
 18 Q. Well which was it? Did you see --  
 19 I want to talk either about the manuscript  
 20 or the poster. Which one you want to talk about?  
 21 A. Let's talk about the poster is fine.  
 22 Q. Have you looked at the manuscript?  
 23 A. I think I saw more data than just the  
 24 poster, yeah.  
 25 Q. Okay. What data else did you see?

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1 A. What?  
 2 Q. What other data did you see?  
 3 A. Besides what?  
 4 Q. I mean, what data did you see about that  
 5 study with respect to the -- the Cleveland Clinic  
 6 study besides the poster?  
 7 A. Well I'm not sure I saw anything, but I  
 8 thought I saw an expanded poster, I guess. I don't --  
 9 I don't know.  
 10 Q. Is it in your box of documents?  
 11 A. I hope so.  
 12 MS. ZIMMERMAN: I didn't see it. I could  
 13 be wrong.  
 14 THE WITNESS: Yeah, I'm sorry.  
 15 MS. ZIMMERMAN: No. No. That's all right.  
 16 Q. By the way, are there -- are there documents  
 17 that you did not print up that you looked on -- that  
 18 you have on your computer?  
 19 A. No.  
 20 Q. So every document you reviewed you printed  
 21 up and highlighted or have done something with it.  
 22 A. Yeah. I don't like to read stuff on the  
 23 computer.  
 24 Q. Okay.  
 25 A. I'm old.

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1 MR. COREY GORDON: Gabe, I'll just  
 2 represent, he hasn't -- the only thing he's seen is  
 3 what was attached to Mont's report. There is no --  
 4 however you want to characterize it, there's no other  
 5 data that he or I or anyone connected with the  
 6 plaintiffs -- or with the -- with this litigation has  
 7 seen.  
 8 Q. So you're sitting here advocating for the  
 9 Bair Hugger as a better device than the Mistral?  
 10 A. I'm not advocating for them. I'm saying  
 11 that after review of the literature I've come to the  
 12 conclusion that the Bair Hugger is not linked in any  
 13 way to harm.  
 14 Q. Okay. And what about -- I mean -- Strike  
 15 that.  
 16 But with respect to patient warming, as long  
 17 as the patient is kept warm, you don't care what  
 18 method is used; correct?  
 19 A. Right now I think there are no data to show  
 20 that if the patients are warmed by anything else,  
 21 particularly after the Kurz study, you have that  
 22 warmer as an additional one. It looked the same.  
 23 Q. Which warmer?  
 24 A. The HEPA -- the forced-air warmer. So  
 25 that's probably the best data I could point to.

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1 Q. Are you aware of the CDC indicating that  
 2 there should be nothing in the OR that blows air?  
 3 MR. COREY GORDON: Object to the form of  
 4 the question, mis --  
 5 A. I've read --  
 6 MR. COREY GORDON: -- misstates the --  
 7 mischaracterizes the evidence.  
 8 A. I've read the document where they said that,  
 9 and actually looked at their in-progress, I guess,  
 10 guideline from December 2016, and they really talk  
 11 about the air-water interface when they're giving that  
 12 statement.  
 13 I should also say that, because I wanted to  
 14 be sure, I called the director of the CDC's quality  
 15 healthcare, I forget what the -- that whole division  
 16 that oversees HICPAC, and she told me they -- you  
 17 know, this wasn't pertaining to forced-air warming, it  
 18 was worry -- their big concern was when, you know, the  
 19 heater-cooler unit was identified as a really source  
 20 of serious infection.  
 21 Q. What was her name?  
 22 A. It is Denise A. Cardo.  
 23 Q. How do you spell that, for the court  
 24 reporter?  
 25 A. C-A-R-D-O.

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<p style="text-align: right;">Page 342</p> <p>1 Q. And when did you contact her?</p> <p>2 A. In the last couple weeks.</p> <p>3 Q. Did you contact her at the request of</p> <p>4 counsel?</p> <p>5 A. No. They didn't know I did that.</p> <p>6 Q. Okay. Did you bill it on your -- in your</p> <p>7 invoice?</p> <p>8 A. No, I didn't.</p> <p>9 Q. Okay. And do you have a record of this</p> <p>10 conversation?</p> <p>11 A. No, I don't.</p> <p>12 Q. How did you get her phone number?</p> <p>13 A. Called CDC, got ahold of her former</p> <p>14 assistant, because the numbers don't carry over</p> <p>15 sometime when there's some movement, and she said,</p> <p>16 well you need to talk to this person's assistant.</p> <p>17 Gave me the assistant, I left a message and asked her</p> <p>18 if there was a good time when I could call.</p> <p>19 MR. ASSAAD: Take a break?</p> <p>20 THE REPORTER: Please. Thank you.</p> <p>21 (Recess taken from 4:57 to 5:05 p.m.)</p> <p>22 BY MR. ASSAAD:</p> <p>23 Q. Doctor, turning to page 62?</p> <p>24 A. Okay.</p> <p>25 Q. 62 begins your critique of the McGovern</p>	<p style="text-align: right;">Page 344</p> <p>1 MR. COREY GORDON: Object to the form of</p> <p>2 the question.</p> <p>3 A. I mean, I was told -- asked to come to a</p> <p>4 meeting to meet them. That's really what there was,</p> <p>5 and we did discuss the study, yes, very much.</p> <p>6 Q. How long did you --</p> <p>7 It was the majority of your discussions;</p> <p>8 correct?</p> <p>9 A. Probably, yeah.</p> <p>10 Q. Okay. And you all got together and figured</p> <p>11 out a way to discredit the McGovern study; correct?</p> <p>12 MR. COREY GORDON: Object to the form of</p> <p>13 the question.</p> <p>14 A. I don't know if I would have used that term.</p> <p>15 To look at it critically.</p> <p>16 Q. To look at the study critically; correct?</p> <p>17 A. Yes. Yeah.</p> <p>18 Q. And let me ask you this. Prior to agreeing</p> <p>19 to be an expert in this case did you look at the</p> <p>20 McGovern study?</p> <p>21 A. No. I don't think I --</p> <p>22 Q. Okay.</p> <p>23 A. -- knew about it.</p> <p>24 Q. Did you --</p> <p>25 Did you do any research to determine whether</p>
<p style="text-align: right;">Page 343</p> <p>1 study; correct?</p> <p>2 A. The clinical arm.</p> <p>3 Q. Yes. Of the McGovern study; correct?</p> <p>4 A. Yeah. Yes.</p> <p>5 Q. And you go on for about, from page 62 to</p> <p>6 page 68; correct?</p> <p>7 A. Let me see. Yes.</p> <p>8 Q. You did not do a critical critique of any</p> <p>9 other study that -- that you looked at, such as you</p> <p>10 did with the McGovern study; correct?</p> <p>11 A. That's probably true.</p> <p>12 Q. Okay. You didn't do any critiques of --</p> <p>13 (Cell phone interruption.)</p> <p>14 MR. COREY GORDON: Sorry.</p> <p>15 Q. -- the Sessler study we just looked at;</p> <p>16 correct?</p> <p>17 A. True.</p> <p>18 Q. You didn't do any critical critiques of the</p> <p>19 Huang study; correct?</p> <p>20 A. Yeah.</p> <p>21 Q. Okay. Or the Moretti study; correct?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. But you decided to have a meeting</p> <p>24 with Dr. Borak and Dr. Holford and yourself to discuss</p> <p>25 the McGovern study; correct?</p>	<p style="text-align: right;">Page 345</p> <p>1 or not you agreed with the -- with the defense in this</p> <p>2 case before you agreed to be an expert?</p> <p>3 A. I spent -- no, just a couple of days, you</p> <p>4 know. So I told you the -- one thing was the timing</p> <p>5 was good, it was interesting, it was a single case.</p> <p>6 And I thought, well, you know, it might be interesting</p> <p>7 to look at this, particularly if you're really just</p> <p>8 asked to learn and they pay you to learn, and that's</p> <p>9 how I thought about it.</p> <p>10 Q. Well they didn't pay you to learn, they paid</p> <p>11 you to be an expert for them in this case.</p> <p>12 MR. COREY GORDON: Object to the form of</p> <p>13 the question, lack of foundation, mischaracterizes</p> <p>14 the evidence.</p> <p>15 Q. It's your understanding that 3M hired you</p> <p>16 just to learn?</p> <p>17 A. 3M didn't hire me.</p> <p>18 Q. The attorneys representing --</p> <p>19 A. The attorneys did, yeah.</p> <p>20 Q. And who do you think was paying the</p> <p>21 attorneys?</p> <p>22 A. 3M.</p> <p>23 Q. Okay. So it's your opinion that 3M or the</p> <p>24 attorneys hired you just to learn?</p> <p>25 A. No. You just asked me why I sort of got</p>